**Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)**

**EudraCT:2018-001904-12**

**PHARMACY MANUAL**

Version 3.0, 8th March 2019

Chief Investigator: Professor Nikola Sprigg

Sponsor: University of Nottingham

Sponsor Reference:18040

|  |  |  |  |
| --- | --- | --- | --- |
| Written by:  (Print & sign) | Bernie Cook |  | Date: |
| Title | Lead Pharmacy Technician – Clinical Trials  (NUH NHS Trust) | |
|  | | | |
| Approved by:  (Print & sign) | Sheila Hodgson |  | Date: |
| Title | Lead Pharmacist – Clinical Trials  (NUH NHS Trust) | |

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**Applicability**

This procedure applies to all pharmacy personnel at participating sites. Its purpose is to ensure that the processes of storing, labelling, ordering, dispensing accounting for and destroying IMP are carried out to the standard required for DASH and in accordance with the applicable ICH-GCP principles.

**Responsibilities**

All personnel carrying out study related activities should be listed on the DASH Authorised Personnel Log and be appropriately trained and familiar with the trial, its protocol and procedures.

For each site a lead pharmacist should be identified. This person will have overall responsibility for the study and will be required to sign a lead pharmacist declaration form and return this to the STU prior to the IMP being received at site

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**2. Abbreviations**

ICH-GCP International Conference on harmonisation – Good Clinical Practice

IMP Investigational Medicinal Product

MA Marketing Authorisation

SmPC Summary of Product Characteristics

SOP Standard Operating Procedure

STU Stroke Trials Unit

PI Principal Investigator

PSF Pharmacy Site File

**3. Study Contacts**

**Chief Investigator: Deputy Chief Investigator:**

Professor Nikola Sprigg Dr Michael Desborough

<Tel:0115> 8231765 <Tel:01865> 447900

Email:nikola.sprigg@nottingham.ac.uk Email:Michael.desborough@ouh.nhs.uk

**DASH Trial Manager & Coordinator:**

Diane Havard

<Tel:0115> 8231775 Fax:0115 8231771

Email: [dash@nottingham.ac.uk](mailto:dash@nottingham.ac.uk)

**Trial Pharmacist:**

Sheila Hodgson

<Tel:0115> 9194450 or 0115 9691169 Ext. 55280

Email:sheila.hodgson@nuh.nhs.uk

**Emergency Contact details** (including unblinding)

Tel:07736 843 592

Tel:07725 580 092  
Tel:07943 470 427

Tel:07798 670 726

**DASH Website** (login details provided to each site separately)

http://dash-1.ac.uk

**DASH documents**

http://dash-1.ac.uk/docs

**4. Introduction**

The study will recruit patients for 12 months. The participant’s involvement in the trial will last for 90 days, from randomisation (day 1) until final follow-up at 90 days.

Trial treatment is administered as desmopressin 20μg (5 x 4mcg/ml) in 50ml sodium chloride 0.9% (total infusion volume of 55mls). Placebo treatment replaces desmopressin with sodium chloride 0.9%, 3 x 2ml in 50ml sodium chloride 0.9% (total infusion volume of 56ml). Doses are administered through a venous cannula over 20 minutes.

**5. Study Medication**

Nottingham University Hospital pharmacy (MIA IMP 19162) will prepare individual blinded treatment packs containing 5 x 1ml glass ampoules desmopressin 4mcg/ml **or** 3 x 2ml sodium chloride 0.9%. These will be non-identical. The ampoules and the outer carton will be labelled in accordance with Annex 13 of Volume 4 of The Rules Governing Medicinal Products in the EU: Good Manufacturing Practices, assuming that the primary and secondary packaging remain together throughout the trial. To facilitate identification, the carton and the ampoules contained within it will be labelled with the same unique pack ID number. Additional labels to identify the trial and subject randomisation number will be provided for attachment to intravenous infusion bags, case report forms and participant’s medical records.

Personnel preparing the injection for administration will not be masked to the treatment allocation as the ampoules of active and placebo injections are of different sizes and the number of ampoules in the cartons is different for active and placebo treatments. The ampoules are labelled only as trial medication so the researchers and patient will remain blinded to treatment allocation. Detailed prescribing and administration instructions will be provided in the treatment pack.

**Desmopressin**

Intravenous desmopressin (DDAVP) 4μg/ml 1ml glass ampoules are a licensed product (Ferring Pharmaceuticals). A SmPC is available.

**Placebo**

Intravenous Sodium Chloride 0.9% will be used as the placebo in this study. Sodium Chloride 0.9% 2ml ampoules are a licensed product. A SmPC is available.

**6. Storage**

IMP packs must be stored in a refrigerator between 2°C and 8°C.

To ensure stability and quality are maintained, the product must be stored correctly upon receipt and for the duration of the study under the conditions specified above. IMP should be stored in a controlled environment, in a trial specific area separated from the general NHS stock. Access should be controlled and limited only to authorised personnel

**Temperature Monitoring**

Records of the actual storage conditions during the period of the study must be maintained.

Pharmacy staff should ensure that the location of temperature logs for the area(s) where the trial medication is stored is referenced in the PSF. (Appendix 1 or PSF section 4). A minimum and maximum temperature must be recorded every weekday as a minimum (excluding bank holidays), with a calibrated temperature monitoring device. Temperature logs must be available for review during monitoring visits, if requested.

**Temperature Excursions**

See instructions below for reporting.

* **< 2°C - DO NOT USE**

Immediately return all affected supplies to local site pharmacy unused. A

temperature excursion form (Appendix 2 or PSF Section 4) should be completed

and forwarded to the DASH Trial Team ([dash@nottingham.ac.uk](mailto:dash@nottingham.ac.uk) or

Fax:0115 8231771), who will advise on the course of action.

* **>8°C to ≤ 25°C - Continue to store in the refrigerator but complete details on the cumulative temperature excursion form** (Appendix 10 or PSF Section 4).Temperature excursions between 9°C and 25°C only need to be reported to the DASH Trial Team, if the cumulative time period out of range is greater than 28 days.(672hours)
* **> 25°C - DO NOT USE**

Immediately return all affected supplies to local site pharmacy unused. A

temperature excursion form (Appendix 2 or PSF Section 4) should be completed

and forwarded to the DASH Trial Team([dash@nottingham.ac.uk](mailto:dash@nottingham.ac.uk) or

Fax:0115 8231771), who will advise on the course of action.

**7. Labelling**

In line with sites local policy, additional labels are permitted.

All IMP’s provided will be labelled in accordance with Annex 13, plus additional site specific information on the outer carton.

**Sample Ampoule Label:**

|  |  |
| --- | --- |
| Store in a refrigerator at 2-8°C For Intravenous use only  **Desmopressin 4 micrograms per 1ml**  **or Placebo Injection**  **Subject Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject ID Number \_\_\_\_\_\_\_\_\_\_\_\_**  **Pack ID XXXXX**  **Batch Number: xxxxxx Expiry Date: xx.xx.xx**  **Sponsor: University of Nottingham, Tel: 0115 8231770**  EudraCT Number 2018-001904-12  Packed by NUH Pharmacy MIA(IMP)19162 |  |

**Sample Outer Carton Label:**

|  |  |
| --- | --- |
| For Clinical Trial Use Only Store in a refrigerator at 2-8°C  For Intravenous Use Only  **Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)**  **Desmopressin 4 microgram per 1ml or**  **Placebo Injections**  To be used as directed in the trial protocol  This pack contains 3 or 5 ampoules of study material  **Subject Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject ID Number \_\_\_\_**  **Date of dispensing \_\_\_\_\_\_\_\_\_\_\_\_ Pack ID XXXXX**  **Batch Number: xxxxx Expiry Date: xx/xx/xx**  **Chief Investigator:** Prof. Nikola Sprigg, University of Nottingham, Clinical Sciences Building, Hucknall Road, NG5 1PB. **Tel: 0115 8231770**  **Sponsor: University of Nottingham**  EudraCT Number 2018-001904-12  Keep out of reach and sight of children  Packed by NUH Pharmacy MIA(IMP)19162 |  |

*Label content will remain as shown above, however the formatting of final versions may vary.*

**8. Ordering & Receipt**

**Initial Order & Resupply**

Ordering and resupply will be under the control of the STU.

Sites will receive notification of pending shipments via email.

Participating sites will be allocated a batch of trial treatment. The container numbers for the batch are tracked by the web-based system to the participating site. When receipt at site is confirmed and temperature records for the transit period have been received and reviewed, containers are released for use in the trial. When the supplies at the participating site reach a pre-determined level a re-order is triggered and a further supply of trial treatment is sent to the participating site.

The study medication will be distributed by Clinical Trials Pharmacy, Nottingham University Hospitals NHS Trust Queens Medical Centre Campus, Derby Road, Nottingham, UK, NG7 2UH.

Sites will receive the shipment within a maximum of two working weeks. A copy of the QP Release Certificate will be included in each shipment.

**Receipt**

Upon receipt of a shipment, it is the pharmacy staff responsibility to:

* Check study drug received against the Acknowledgement of Receipt Form

(Appendix 3 ).

* Check that supplies are received undamaged
* Sign the Acknowledgement of Receipt form and fax or email to the DASH Trial

Manager

Tel:0115 8231775 or Fax:0115 8231771, Email: [dash@nottingham.ac.uk](mailto:dash@nottingham.ac.uk) **and**

NUH Pharmacy Clinical Trials ([qmc.pharmacyclintrial@nuh.nhs.uk](mailto:qmc.pharmacyclintrial@nuh.nhs.uk) or Fax:0115 91954450).

* Quarantine supplies and await confirmation of suitability for use/further instruction from DASH Trial Manager .
* Record all supplies on the Pharmacy – IMP Site Inventory Log

(Appendix 5 or PSF Section 1).

* Login to the DASH website (<http://dash-1.ac.uk>) and mark packs as received.
* File the Acknowledgement of Receipt forms in the PSF Section 3.

Any complaints related to product quality must be submitted via email to the DASH Trial Manager Tel:0115 8231775 Fax:0115 8231771 Email: dash@nottingham.ac.uk who will forward to NUH Pharmacy Clinical Trials as appropriate.

**9. Randomisation**

All participants eligible for inclusion will be randomised centrally using a secure internet

in real time.

Randomisation will allocate a number corresponding to a treatment pack and the participant will receive treatment from the allocated numbered pack.

Personnel preparing the injection for administration will not be blinded to the treatment allocation as the ampoules of active and placebo injections are of different sizes and the number of ampoules in each carton is different for active and placebo treatments.

In the event of computer failure (for example: server failure), investigators will follow the working practice document for computer system disaster recovery, which will allow the participant to be randomised following standardised operating procedure. This document will be given to the PI at participating sites.

**10. Prescribing**

Only the PI or qualified medical doctors delegated with the responsibility of prescribing by the PI should prescribe medication for study patients.

Refer to Prescribing and Administration Guide included in each treatment pack (Appendix 9)

Additional labels to identify the trial title and subject randomisation number will be provided for attachment to intravenous infusion bags, case report forms and participants medical records.

**Sample Label**

This patient has been recruited into the DASH trial. Desmopressin for the reversal of Antiplatelet drugs in Stroke due to Haemorrhage

Randomisation No:

Sponsor: The University of Nottingham. Ref: 18040

Please call the DASH Office if you have any queries.

(+44) 115 82 31672

**Please retain these notes until 31/12/2028 v1.0 20181220**

**11. Dispensing & Accountability**

The local site investigator is responsible for ensuring trial treatment accountability, including reconciliation of trial treatment and maintenance of trial treatment records, throughout the course of the study in accordance with UK regulatory requirements. Responsibility can be delegated to the site pharmacy clinical trials staff.

**Pharmacy**

The site pharmacy will be responsible for issuing the IMP to the Stroke Unit at site. A DASH IMP Transfer Request Form (Appendix 4) must be completed.

The pharmacy clinical trials staff will check that the person completing the Transfer Request Form has delegated responsibility by the PI by reference to the study delegation log.

All IMP issued by Pharmacy to the Stroke Unit must be recorded on the Pharmacy IMP Inventory Log (Appendix 5) and details completed on the DASH IMP Transfer Request Form.

**Stroke Unit**

The Research Team on the Stroke Unit will be responsible for dispensing the IMP to subjects.

Upon receipt of IMP from the site Pharmacy, allocation of IMP to a subject or return of used/unused packs to the site Pharmacy, the details should be recorded on the Stroke Unit IMP Accountability Log (Appendix 6).

Following randomisation, the participant will be allocated a treatment pack number. Specifically authorised personnel on the delegation log will retrieve the appropriate pack number and complete the participant name, date of randomisation and participant number. Pack number allocation will be checked and countersigned by the research staff and the nursing staff administering the treatment. The empty IMP boxes do not need to be returned to pharmacy. They can be disposed of on the Stroke Unit once the accountability log has been completed. Refer to Appendix 9, DASH Prescribing & Administration Guide)

If returning IMP to the site Pharmacy from the Stroke Unit (e.g. unused or expired pack) a DASH Return of Clinical Supplies form (Appendix 7 or PSF Section 3) must be completed to accompany the packs. The Stroke Unit IMP Accountability Log should be completed, documenting return to the site Pharmacy. Any unused ampoules must be recorded on the Stroke Unit IMP Accountability Log, using the ‘comments’ section for the Pack Number returned.

In the event a treatment pack is damaged, the site should inform the DASH Trial Manager in order that the website can be updated.

If any packs are lost, the site investigator should complete a non-participant protocol violation CRF or, if unable to do this, they should contact the DASH Trial Manager.

**12. Replacement IMP Packs**

If the allocated IMP pack is lost or damaged prior to administration, the IMP pack should be replaced. The site team should contact the DASH Trial Manager (or an emergency study contact if out of hours)

**13. Code break & Unblinding**

Clinicians, patients and outcome assessors (clinical, radiological and haematological assessors) will be blinded to treatment allocation.

In general there should be no need to unblind the allocated treatment. If a contraindication to desmopressin develops after randomisation (e.g. clinical evidence of thrombosis), the trial treatment should simply be stopped. Unblinding should be done only in those rare cases when the doctor believes that clinical management depends importantly upon knowledge of whether the patient received desmopressin or placebo. In those few cases when urgent unblinding is considered necessary, the emergency telephone number should be telephoned, giving the name of the doctor authorising unblinding and the treatment pack number. The caller will then be told whether the patient received desmopressin or placebo. The rate of unblinding will be monitored and audited. The emergency contact details will be given to the investigators at participating sites.

Emergency Out of Hours contacts

Nikola Sprigg – Tel: 07725 580092

Mike Desborough – Tel:07736 843592

Philip Bath – 07798 670726

**14. Destruction**

Retain all returned unused ampoules in pharmacy until permission is given to destroy

Destruction should be carried out by the site Pharmacy according to local SOPs, only after any discrepancies have been investigated and satisfactorily explained. Reconciliation will be accepted and confirmed in writing by the sponsor/representative prior to any destruction taking place. Destruction will be documented on the DASH IMP Destruction Log (Appendix 8 or PSF Section 3), which should be filed in the PSF.

Destruction of any study medication that is unused at the end of the study or has expired should only be completed following written approval from the sponsor.

Once destruction of packs is completed the site pharmacy staff should login to the DASH website and mark the appropriate pack(s) as destroyed.

**15. Version Control**

|  |  |  |  |
| --- | --- | --- | --- |
| Version Number | Amended By | Amendment Date | Changes implemented by this amendment |
| TWO | Bernie Cook/  Sheila Hodgson | 11th February 2019 | Temperature excursion reporting procedure updated  Prescribing and administration guide updated. |
| THREE | Bernie Cook/Sheila Hodgson | 13th March 2019 | Temperature Excursion reporting procedure updated  Update of DASH Trial Manager contact details |
|  |  |  |  |

**Appendix 1**

**TEMPERATURE LOG**

**Temperature Range 2ºC to 8ºC**

**DASH (EudraCT:2018-001904-12)**

**Investigator:…………………………. Site:…………………**

**Month:…………… Year:………..**

**Thermometer Location/Thermometer Number: ………………………………………………..…………**

**Follow local procedures and Inform DASH Trial Manager if temperature is outside permitted range**

**(**<Tel:0115> 8231775 Fax:0115 8231771 Email: [dash@nottingham.ac.uk](mailto:dash@nottingham.ac.uk))

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Date** | **Time** | **Temperature °C** | | | **Recorded by** | **Comments** |
| **24 hour clock** | **Current** | **Minimum** | **Maximum** |
| **01** |  |  |  |  |  |  |
| **02** |  |  |  |  |  |  |
| **03** |  |  |  |  |  |  |
| **04** |  |  |  |  |  |  |
| **05** |  |  |  |  |  |  |
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| **31** |  |  |  |  |  |  |

**Appendix 2**

|  |  |  |
| --- | --- | --- |
| **Temperature Excursion Reporting Form** | | |
| **Desmopressin For Reversal Of Antiplatelet Drugs In Stroke Due To Haemorrhage**  **(DASH)**  **Sponsor:** University of Nottingham  **EudraCT:** 2018-001904-12 | | |
|  |  |  |
| **Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Site:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Site No:\_\_\_\_\_\_\_\_\_\_\_\_** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Start Date & Time of Temperature Excursion:** | | \_\_\_ / \_\_\_ /\_\_\_\_\_\_  \_\_\_\_\_:\_\_\_\_\_ | | **End Date & Time of Temperature Excursion:** | | \_\_\_ / \_\_\_ /\_\_\_\_\_\_  \_\_\_\_\_:\_\_\_\_\_ | |
| **Duration of Temperature Excursion (hours/days):** | |  | | **Minimum Temperature Recorded:** | |  | |
| **Maximum Temperature Recorded:** | |  | |
| **Reason for temperature excursion:** | |  | | | | | |
| **Pack numbers affected by excursion** | |  | | | | | |
| **Date DASH Trial Manager informed:** | | \_\_\_ / \_\_\_ /\_\_\_\_\_\_ | | | | | |
| **Action taken by Site / Pharmacy:** | | | | | | | |
|  | | | | | | | |
| **Reported By:**  **Name:** |  | | **Signature:** |  | **Date:** | | \_\_\_/\_\_\_ /\_\_\_\_\_ |
|  | | | | | | | |
| **Reviewed By:**  **Trial Manager:** |  | | **Signature:** |  | **Date:** | | \_\_\_/\_\_\_ /\_\_\_\_\_ |
| **Outcome:** |  | | | | | | |

**Appendix 3**

**Nottingham University Hospitals**

**Pharmacy Clinical Trials Department**

**Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)**

**RECEIPT OF CLINICAL TRIAL SUPPLIES**

**Despatched To: Despatched from: S Hodgson/S Hodgkinson/B Cook**

**Pharmacy Clinical Trials Queens Medical Centre Campus**

**Nottingham University Hospitals NHS Trust**

**Derby Road**

**Nottingham, NG7 2UH**

**Date dispatched:**

**Investigational Medicinal Products enclosed as listed below: -**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description** | **Batch Number &**  **Expiry Date** | **Number of packs supplied** | **Individual Pack Number(s) supplied** |
| Treatment Packs containing:  Desmopressin 4microgram/ml injection **or** Sodium Chloride 0.9% injection (placebo) | BN:  Exp: |  |  |

**Please complete information below and fax or email to the DASH Trial Manager** (<Tel:0115> 8231775, Fax:0115 8231771 Email: [dash@nottingham.ac.uk](mailto:dash@nottingham.ac.uk)) **and NUH Pharmacy Clinical Trials** (qmc.pharmacyclintrial@nuh.nhs.uk or Fax:0115 91954450)

Drugs received: (Date & time): \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_am/pm

* All received as described and undamaged? YES / NO (Circle as applicable)
* Quarantined and awaiting confirmation that all packs received within the specified temperature range? YES / NO (Circle as applicable)

Please comment on any discrepancies:…………………………………………………………………………………………………………………………………………………………………………..…..

Received By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature + Print Name)

Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Print Position)

**Appendix 4**

**CLINICAL TRIALS TRANSFER REQUEST FORM**

**Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage**

**(DASH)**

**EudraCT:2018-001904-12**

**Chief Investigator: Professor N Sprigg/Dr Michael Desborough**

**Local Investigator:…………………………**

**Please Supply:**

**Treatment packs containing:**

**3 x 2ml ampoules Desmopressin 4microgram/ml**

**or**

**5 x 1ml ampoules Sodium Chloride 0.9%**

**Date Required: …………………………**

**Ordered by (sign): …………………………………… Bleep/Ext No: …………………**

**Name in Block Capitals: …………………………… Date: …………**

***FOR PHARMACY USE ONLY***

**Issued by: …………………………………………… Date: ………………………..**

**Number of packs issued:………………………………**

**Pack Numbers Issued:……………………………………………………..**

**……………………………………………………………………………………………….**

**Checked by: ………………………………………… Date: ………………………..**

**Collected by: ……………………………………….. Date: ……………………….**

**Appendix 5**

|  |  |  |
| --- | --- | --- |
| **Nottingham University Hospitals NHS Trust**  **Pharmacy Department Clinical Trials Service** | | |
| **Pharmacy - Site IMP Inventory Log** | | |
| **Protocol Name:**  Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH) | **Protocol/EudraCT Number:**  2018-001904-12 | |
| **IMP (form and strength):**  Desmopressin 4microgram/ml or Placebo Injection | **Chief Investigator:**  Professor Nikola Sprigg/  Dr Michael Desborough  **Principle Investigator:** | **Site number:** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date  dd/mmm/yy | Pack  Number | Batch number | Expiry | Quantity  R : Received  D: Dispensed  E: Expired  DES: Destroyed  R D E /DES | | | Issued To | Balance | Received / Disp By | Checked By | Additional Comments | Checked By Sponsor |
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**Appendix 6**

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| **Nottingham University Hospitals NHS Trust**  **Pharmacy Department Clinical Trials Service** | | |
| **Stroke Unit – IMP Accountability Log** | | |
| **Protocol Name:**  Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH) | **Protocol/ EudraCT Number:**  2018-001904-12 | |
| **IMP (form and strength):**  Desmopressin 4microgram/ml or Placebo Injection | **Chief Investigator:**  Professor Nikola Sprigg/  Dr Michael Desborough  **Principal Investigator:** | **Site number:** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Receipt** | | | | **Issued to Subject** | | | | | | **Return to Pharmacy** | | | Comments |
| Date  Received (dd/mmm/yy) | Pack ID  Number | Expiry  Date | Received By | Date Issued  (dd/mmm/yy) | Subject Trial ID Number | Subject  Name | Subject Hospital Number | Issued  By | Check By | Date  Returned  to  Pharmacy  (dd/mmm/yy) | Quantity Returned | Returned By |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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**Appendix 7**

**Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)**

EudraCT Number:2018-001904-12

Local Investigator: **………………………………………………..** Site:……………………………..

**The following clinical trial supplies have been returned to pharmacy**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description** | **Used or Unused**  **Pack(s)** | **Number of Packs Returned** | **Pack ID Number(s)** |
| **Pack(s) containing:**  Desmopressin 4µg/ml ampoules or Sodium Chloride 0.9% ampoules |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Stroke Unit Staff** | | **Date** | **Pharmacy Staff** | | **Date** |
| Returned by |  |  | Checked & Received by |  |  |
| Print Name |  | Print  Name |  |

**For Pharmacy Use Only**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Action** | | **Signature & Date** | **Outcome** | **Signature & Date** |
| To be quarantined in pharmacy |  |  |  |  |
| To be sent for destruction |  |  |  |  |

1 copy to investigator file 1 copy to pharmacy file

**Appendix 8**

**RECORD OF IMP DESTRUCTION**

**At the request of:**

**Sponsor: University of Nottingham Sponsor Representative: …………………………………  
Address:** East Atrium, Jubilee Conference Centre, Triumph Road, Nottingham. NG8 1DH

*(Attach a copy of the authorisation email/correspondence)*

***The following IMP have been sent for destruction by pharmacy according to local SOPs for destruction of pharmaceutical waste***

**Study Title:** Desmopressin For Reversal Of Antiplatelet Drugs In Stroke Due To Haemorrhage (DASH)

**EudraCT Number:**2018-001904-12

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Pack ID Number** | **Patient Number**  (if applicable) | **Description** | **Quantity**  (number of ampoules) | **Batch Number** | **Expiry Date** |
|  |  | Pack containing Desmopressin 4µg/ml 1ml amps or Sodium Chloride 0.9% 2ml amps |  |  |  |
|  |  | Pack containing Desmopressin 4µg/ml 1ml amps or Sodium Chloride 0.9% 2ml amps |  |  |  |
|  |  | Pack containing Desmopressin 4µg/ml 1ml amps or Sodium Chloride 0.9% 2ml amps |  |  |  |
|  |  | Pack containing Desmopressin 4µg/ml 1ml amps or Sodium Chloride 0.9% 2ml amps |  |  |  |
|  |  | Pack containing Desmopressin 4µg/ml 1ml amps or Sodium Chloride 0.9% 2ml amps |  |  |  |

Documented for destruction by:……………………………………………………….Date:……………………….

Name (PRINT): ……………………………………………..Title:……………………………...

Verified and sent for destruction by.........................................................................Date:.................................

Name (PRINT):.…….……………………………………….Title……………………….………

Completed forms to be filed in the Pharmacy File.

**Appendix 9**

|  |  |
| --- | --- |
| **Study Title** | **Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)** |
| **Protocol No** | **EudraCT Number 2018-001904-12** |

**Prescribing and administration guide**

**At randomisation a subject is allocated a subject ID number and a corresponding treatment pack ID number from the stock available at site**

Investigational medicinal product (IMP) is prescribed on the participants inpatient treatment chart by a medically qualified individual **who is authorised to prescribe for this study** (refer to trial delegation log for sample signatures.)

In the ONCE ONLY/PRE-OPERATIVE MEDICINES AND PGDS section of the chart prescribe:

**DASH STUDY Subject ID Number XXX Pack ID XXX**

**Total contents of pack: 3 or 5 ampoules (containing Desmopressin 20micrograms or 0.9% sodium chloride) added to 50ml Sodium Chloride 0.9% administered as an IV infusion over 20 minutes .**

A locally approved additive label and an additional trial identifying label (Pharmacy Manual section 10) should be attached to each infusion bag.

**Dispensing and Administration**

* select the pack labelled **with the required pack ID** from the stock held in the trials cupboard
* add subject name subject ID number and date of dispensing to the label on the outer packaging
* add subject name and subject ID number to each ampoule label.
* enter subject details in the accountability log against the allocated pack ID

Administer in accordance with the prescription.

**Empty packaging and used ampoules can be disposed of on the ward after completion of accountability log. Unused IMP should be returned to clinical trials pharmacy.**

Temperature excursions below 2◦C and above 8◦C should be reported to the clinical trials pharmacy and the trial office as soon as possible

**Appendix 10**

**Desmopressin for reversal of Antiplatelet drugs in Stroke due to Haemorrhage (DASH)**

**EudraCT:2018-001904-12**

Site:………………………………………………… Investigator:………………………………

**Cumulative Temperature Excursion Form**

**\*\*USE A SEPARATE LOG FOR EACH SUPPLY RECEIVED FROM PHARMACY\*\***

|  |  |  |
| --- | --- | --- |
| Treatment kits containing:  Desmopressin 4microgram/ml injection **or** Sodium Chloride 0.9% injection (placebo) | Treatment Pack Numbers Received |  |
| Date Received |  |

**Desmopressin should be stored at 2°C to 8°C**

* **< 2°C – DO NOT USE** - return IMP to local site pharmacy unused and report as a temperature excursion
* **>8°C to ≤ 25°C – IMP can be stored safely for up to 28 days (= 672 hours)**

***All excursions between 9°C and 25°C must be documented below.***

Each individual temperature excursion contributes cumulatively to the 28 day (= 672 hour) time period. If the cumulative time period out of range is ≥ 28 days (= 672hours), return IMP to local site pharmacy unused and report as a temperature excursion

* **>25°C - DO NOT USE** - return IMP to local site pharmacy unused and report as a temperature excursion

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date | Number of packs affected | Pack numbers affected | Maximum Temperature  Recorded (°C) | Length of time out of range | **Cumulative time** out of range | Further details and action taken by site |
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|  |  |  |  |  |  | Continue overleaf |
| Date | Number of packs affected | Pack numbers affected | Temperature  Recorded (°C) | Length of time out of range | Cumulative time out of range | Further details and action taken by site |
|  |  |  |  |  |  |  |
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Completed by:

Name:………………………………………………………………….. Signature:……………………………………………………

Trial Role:…………………………………………………………….. Date:…………………………………..

(DD-MM-YYYY)

**On completion, email this form to the Dash Trial Team**

For Trials office Use only:

Reviewed by:……………………………………………………..……. Signature:………………….…………………………………………

Trial Role:……………………………………………………..………….. Date:………………………..………………..

(DD-MM-YYYY)

Comments:

**(**[dash@nottingham.ac.uk](mailto:dash@nottingham.ac.uk)**)**