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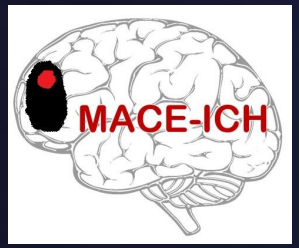
Research & Innovation

MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH): a feasibility trial

PHARMACY TRAINING



IRAS: 1004870

CTA: 19162/0239/001-0001

Chief Investigator: Dr Kailash Krishnan

Consultant Stroke Physician, Nottingham University Hospitals NHS Trust

Associate Professor of Stroke Medicine, University of Nottingham

FUNDED BY
NIHR | National Institute for Health and Care Research

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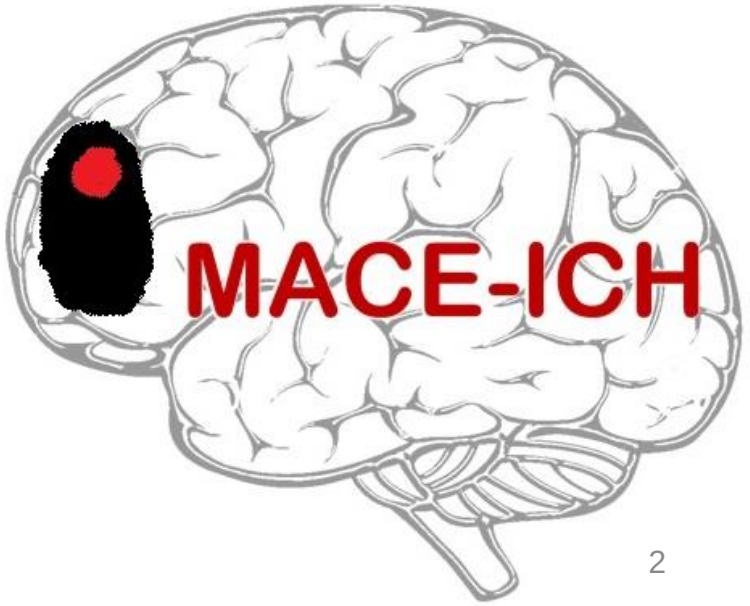


Funding disclosures

- MACE-ICH is funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme, grant reference NIHR-203080

Trial Registration:	ISRCTN15383301
CTA reference:	19162/0239/001-0001
EudraCT Number:	2022-000283-22
IRAS Project ID:	1004870
Trial Sponsor:	Nottingham University Hospitals NHS Trust

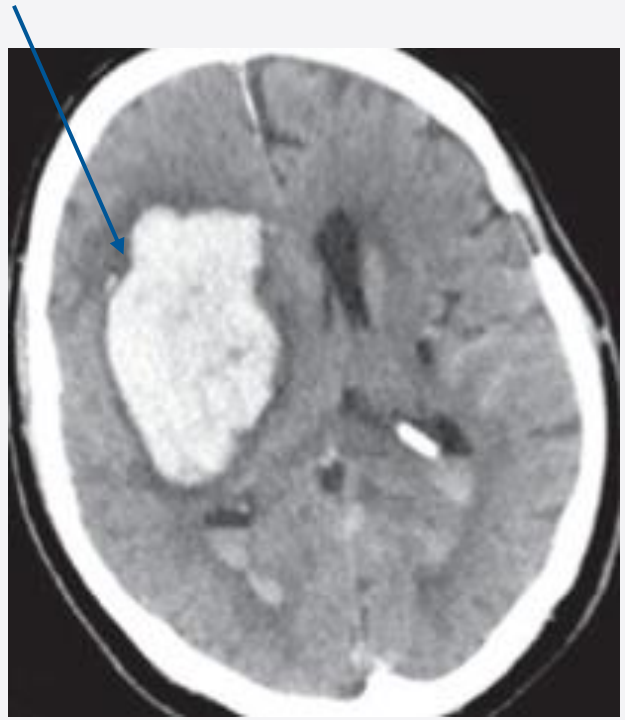
FUNDED BY
NIHR | National Institute for Health and Care Research

This project is funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR-203080). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Background

Intracerebral Haemorrhage (ICH)

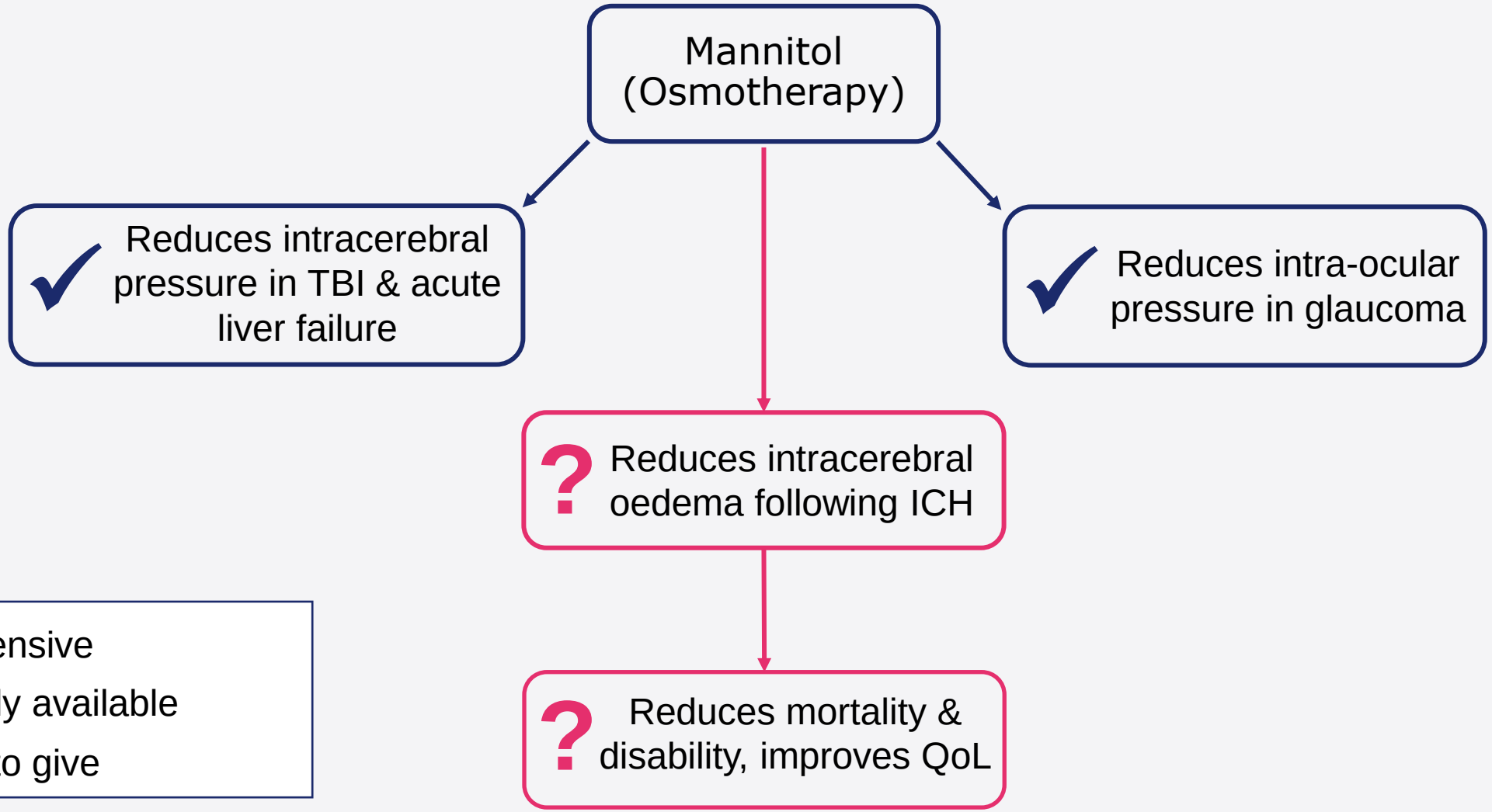
- ~22,500 ICHs each year in UK.
- ~1,500 result in severe brain swelling.
- Greater brain swelling/oedema ➔ death or severe disability (mRS =4-5)
- Mortality/disability following ICHs is significantly higher than ischaemic strokes.



Existing treatment

- Very limited:
  - Surgical decompression? Weak evidence. High risk of complication, particularly for elderly. Not routinely available.
  - Corticosteroids? No evidence. Likely to worsen patient's condition.
  - Osmotherapy? A potential solution?

Rationale



- ✓ Inexpensive
- ✓ Readily available
- ✓ Easy to give

Study Design, Objectives and Outcomes

STUDY DESIGN: A multicentre, prospective, randomised, open-label, blinded-endpoint trial (of mannitol vs standard care)

PRIMARY

Objective: To determine the feasibility and inform the design and conduct of an adequately powered, pragmatic, prospective multi-centre RCT testing mannitol as a treatment for cerebral oedema in spontaneous ICH.

Outcomes:

- No. of patients screened
- No. of patients eligible
- No. of patients screen-failed
- Recruitment rate
- Treatment adherence
- General feasibility

SECONDARY

Objective: To provide preliminary data on the effect of mannitol on secondary outcomes including clinical, radiological, laboratory, safety and health-economics.

Outcomes:

- Assessment scores (GCS, NIHSS, mRS, etc)
- Changes in oedema
- Health economics
- Safety outcomes (death, sepsis, thrombophlebitis, hypotension, renal impairment, hyper/hyponatremia)

Eligibility

Inclusion criteria

- Adults ≥18 years
- Spontaneous ICH (confirmed by brain imaging) with estimated largest diameter >2cm
- ≤72 hours since onset (or from last seen healthy)
- Cerebral oedema with or without evidence of mass effect

  OR
- At risk of developing oedema (limited GCS <9 (eye opening and motor only) and NIHSS>8)
- Signed consent (participant, personal or professional representative or independent physician).

Exclusion criteria

- GCS<5
- Premorbid mRS >3
- Isolated subarachnoid haemorrhage
- Haemorrhage known to be from: trauma or venous thrombosis or arteriovenous malformation or brain tumour or transformation of cerebral infarct or cerebral aneurysm or thrombolytic drug
- Known hypersensitivity to mannitol
- **Severe renal failure (e-GFR<30ml/min or dialysis)**
- Severe pulmonary oedema/cardiac failure
- Hypotension at baseline (SBP <90 mm Hg)
- Anuria
- Patient unwilling to participate
- Geographical or other factors which prohibit follow-up
- Pre-existing comorbidity with pre-ictal life expectancy <6 months
- Severe dementia
- Planned for palliative care
- **Severe hypernatremia (sodium >160 mmol)**
- **Severe hyponatremia (sodium <125 mmol)**
- Patients in whom peripheral intravenous cannula cannot be placed
- Women of child-bearing potential with a positive pregnancy test at the time of admission, or lactating
- Planned neurosurgery

MACE-ICH

MACE-ICH Database

Delegation log/database access

https://stroke.nottingham.ac.uk/mace-ich/live/

- Sign off by the PI via the electronic delegation log will allow access to the trial database
- Request access by emailing mace-ich@nottingham.ac.uk along with:
  - Signed CV and GCP (both within last 2 years or as per local policy)
  - Signed training log (either live training or self-directed)
- Account details will then be sent via email
- Staff member will need to accept invitation to participate, which will send a notification to PI
- PI will need to log in and sign off each staff member, which adds the staff member to the online delegation log and database access is granted.
- **Investigators may only work on the trial once signed off on the delegation log**

Log ID	Investigator name/ID	Certificate/ date assessed or trained	Number of correct answers/score		Roles and responsibilities*	Delegation log status
13	[redacted]	P6Y3N6 3 Jun 2021	-	-	Site investigator BFHIJKLNOPQRSTY	9 Aug 2021 12:10 Authorised [redacted]
14	[redacted]	Y3K6X6 3 Jun 2021	-	-	Site investigator BFHIJKLNOPQRSTY	9 Aug 2021 12:10 Authorised [redacted]

The PI must select whether code J should be applied as a delegated role to take consent (medics only). Code T should be applied as a delegated role to collect trial related blood samples

Randomisation

Online randomisation process

- Patients will be randomised 1:1:1 to receive either:
  - Standard care plus 1 g/kg 10% single dose mannitol infusion at 10ml/min
  - Standard care plus 1 g/kg 10% mannitol at 10ml/min followed by a second dose 1 g/kg repeated at 24 hours
  - Standard care alone
- Randomisation will be performed locally using the trial's secure internet site

- Log into the MACE-ICH online database (https://stroke.nottingham.ac.uk/mace-ich/live/)
- Click to randomise a new patient
- Confirm the patient's eligibility and complete the randomisation form
- Once the form has been submitted, the database will display the allocated treatment
- An email will be sent to staff as confirmation

Investigational Medicinal Product (IMP)

IMP supply and handling

- **IMP characteristics**
  - Intravenous mannitol (Mannitol 10% solution for Infusion BP, Baxter Healthcare Limited PL 00116/0367)
- **IMP supply**
  - Sites will use their own mannitol from standard NHS hospital supplies
- **IMP storage**
  - The IMP will be kept in a secure, limited access storage area, such as a clinical room used for other drug storage and/or preparation.
  - IMP may be kept on the relevant ward/department to be accessible and allow treatment to start promptly as soon as the patient is randomised.
  - Room temperature (20-30°C).
  - Sites should follow their standard procedures for temperature monitoring (ideally a min and max temperature every weekday (excluding bank holidays)
  - Avoid sudden shock of the product (e.g. dropping) to prevent crystallisation.
  - The IMP will be kept as ring-fenced trial medication with study specific labelling

Labelling

Batch Number, Expiry Date and Storage Conditions will be included on the original pack labelling.

To comply with Annex 13 labelling requirements, the following label should be added to the infusion bag:

For Intravenous use only

MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH)
Mannitol Infusion 10% (500ml)
To be infused in accordance with the protocol.

Participant Name _____
Participant ID Number _____
Chief Investigator Dr Kailash Krishnan
Sponsor: Nottingham University Hospitals NHS Trust

EudraCT Number 2022-000283-22

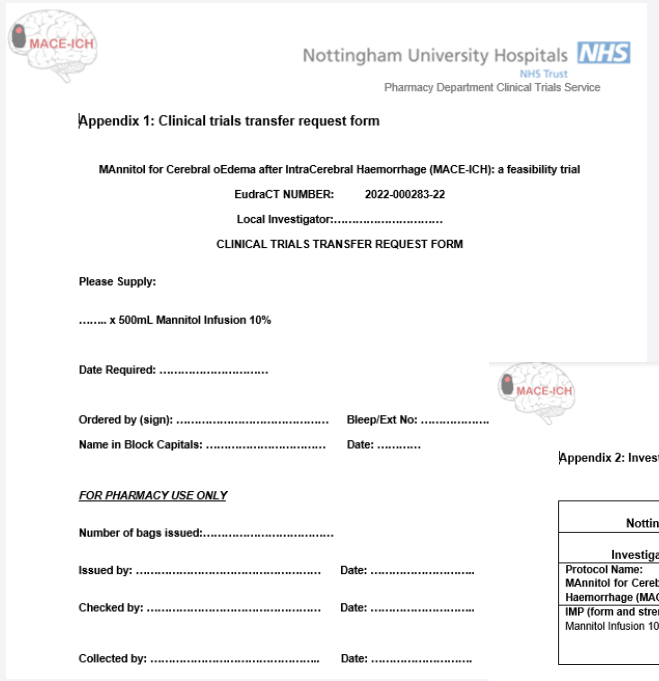
Investigational Medicinal Product (IMP)

IMP dispensing and accountability

Local pharmacy will maintain accountability to record issuing of IMP and return of unused stock.

Pharmacy

- Local pharmacy will be responsible for issuing the IMP to the Stroke Unit or relevant ward or department at site:
  - A MACE-ICH IMP Transfer Request Form must be completed
  - The pharmacy clinical trials staff will check that the person completing the Transfer Request Form has delegated responsibility by the PI
  - All IMP issued by Pharmacy to the Stroke Unit or relevant ward or department must be recorded on the MACE-ICH Pharmacy IMP Inventory Log



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Appendix 1: Clinical trials transfer request form

MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH): a feasibility trial

EudraCT NUMBER: 2022-000283-22

Local Investigator:.....

CLINICAL TRIALS TRANSFER REQUEST FORM

Please Supply:

..... x 500mL Mannitol Infusion 10%

Date Required: .....

Ordered by (sign): ..... Bleep/Ext No: .....

Name in Block Capitals: ..... Date: .....

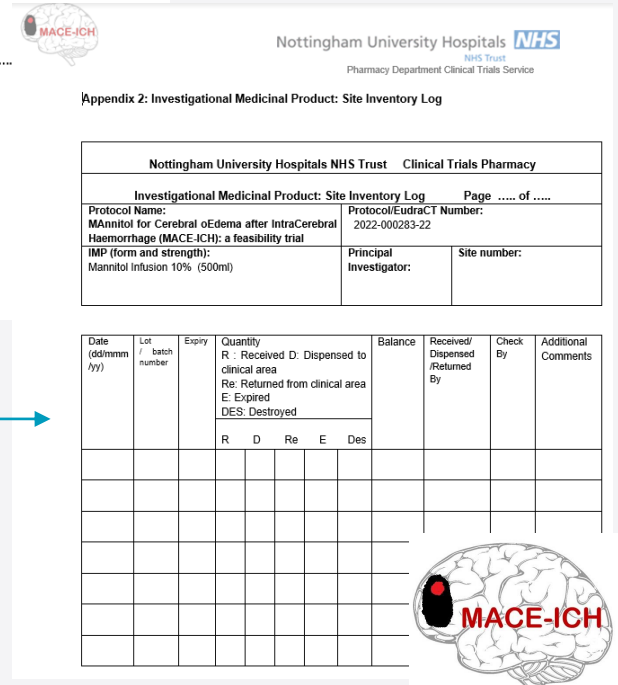
FOR PHARMACY USE ONLY

Number of bags issued:.....

Issued by: ..... Date: .....

Checked by: ..... Date: .....

Collected by: ..... Date: .....



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Appendix 2: Investigational Medicinal Product: Site Inventory Log

Nottingham University Hospitals NHS Trust Clinical Trials Pharmacy		
Investigational Medicinal Product: Site Inventory Log Page ..... of		
Protocol Name: MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH): a feasibility trial	Protocol/EudraCT Number: 2022-000283-22	
IMP (form and strength): Mannitol Infusion 10% (500ml)	Principal Investigator:	Site number:

Date (dd/mmm /yy)	Lot / batch number	Expiry	Quantity R : Received D: Dispensed to clinical area Re: Returned from clinical area E: Expired DES: Destroyed					Balance	Received/ Dispensed /Returned By	Check By	Additional Comments
			R	D	Re	E	Des				

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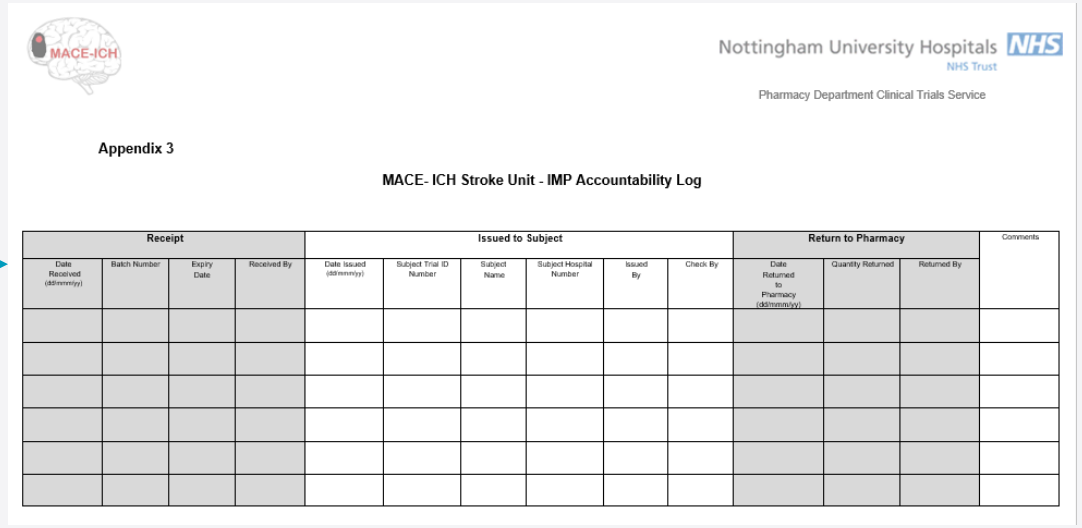
Investigational Medicinal Product (IMP)

IMP dispensing and accountability

Stroke Unit/Ward/Department

- Upon receipt of IMP from the site Pharmacy, the details should be recorded on the MACE-ICH Stroke Unit IMP Accountability Log
- Following randomisation of a participant to treatment arm 1 or treatment arm 2, an intravenous infusion bag should be selected from the available trial stock and the participant name and trial number added to the label on the infusion bag.
- If returning IMP to the site Pharmacy (e.g. unused or expired pack) a MACE-ICH Return of Clinical Supplies form must be completed to accompany the packs. The Stroke Unit IMP Accountability Log should be completed, documenting return to the site Pharmacy.



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Appendix 3

MACE- ICH Stroke Unit - IMP Accountability Log

Receipt				Issued to Subject						Return to Pharmacy			Comments
Date Received (dd/mmm/yy)	Batch 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 4

RETURN OF CLINICAL TRIAL SUPPLIES

MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage (MACE-ICH): a feasibility trial

Local Investigator: ..... Site:.....

The following clinical trial supplies have been returned to pharmacy

Description	Number of Bags Returned	Batch Number	Expiry Date
Mannitol Infusion 10% 500ml			

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			
To be returned to Stock			

1 copy to investigator file 1 copy to pharmacy file

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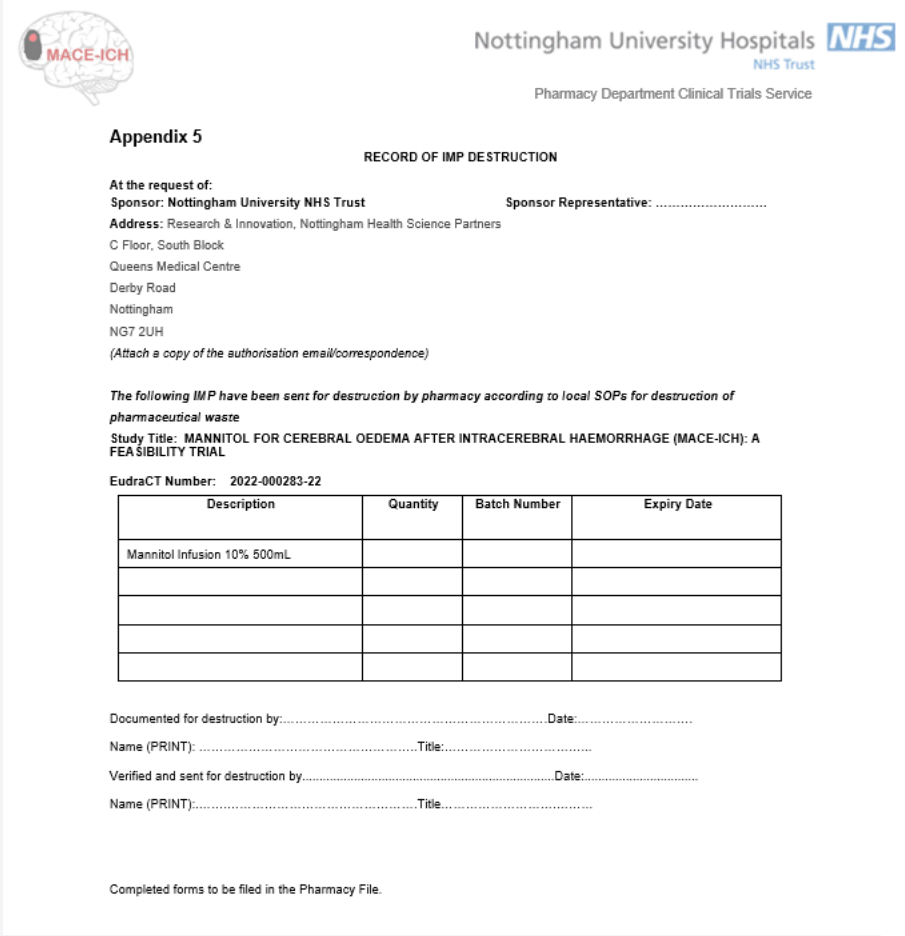
Investigational Medicinal Product (IMP)

IMP dispensing and accountability

IMP destruction

- Retain all returned unused infusion bags 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 MACE-ICH IMP Destruction Log which should be filed in the pharmacy site file.
- 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



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Appendix 5

RECORD OF IMP DESTRUCTION

At the request of:
Sponsor: Nottingham University NHS Trust **Sponsor Representative:** .....
Address: Research & Innovation, Nottingham Health Science Partners
C Floor, South Block
Queens Medical Centre
Derby Road
Nottingham
NG7 2UH
(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: MANNITOL FOR CEREBRAL OEDEMA AFTER INTRACEREBRAL HAEMORRHAGE (MACE-ICH): A FEASIBILITY TRIAL

EudraCT Number: 2022-000283-22

Description	Quantity	Batch Number	Expiry Date
Mannitol Infusion 10% 500mL			

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.

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Investigational Medicinal Product (IMP)

Alternative IMP labelling & accountability process

If preferable, research delivery teams (as opposed to pharmacy) can be responsible for IMP labelling and accountability, but the local process needs to be documented on a file note and sent to the coordinating centre (and filed in the ISF). The following will be acceptable if IMP is already stored on the ward:

1. The research team can overlabel infusion bags with the MACE-ICH label either at the point when a participant is recruited and randomised to receive mannitol OR prior to recruitment such that it is 'ring-fenced' for use in the trial [sites to indicate their local process].
2. The research team will complete the 'Stroke unit accountability log' (Appendix 3) to document IMP administered to participants. The research team will need to retain this in the ISF and email a copy to the coordinating centre upon request.
3. It won't be necessary for the research team to complete the 'IMP transfer request form' (Appendix 1) as the IMP will already be on the ward. Nor will it be necessary for pharmacy to complete the 'Pharmacy IMP inventory log' (Appendix 2) as they will maintain their own local records relating to the IMP being issued/returned to/from the ward.
4. Unused/expired/damaged infusion bags will be destroyed as per local Trust procedures so there is no need for research teams/pharmacy to complete the 'Return of clinical supplies form' (Appendix 4) nor the 'Record of IMP destruction' (Appendix 5). Sites need to confirm their local process on the file note.

Investigational Medicinal Product (IMP)

IMP prescription and administration

- **Prescribing the IMP**
  - IMP should be prescribed by appropriately trained medical practitioners.
    - ***Dr's do not need to be on delegation log to prescribe***
  - Record on the patient's drug chart or on the electronic prescribing and medicines administration system, referenced as part of the MACE-ICH trial.
  - The research team will record administration of the IMP on each participant's CRF, including dates, quantity, batch/serial numbers, expiry dates and trial number assigned to each participant.

- **Administering the IMP**
  - The treatment should be administered by clinical staff in accordance with local policy.
  - The infusion should be visually inspected before administration to ensure it is free from particles or crystallisation and suitable for use.
  - Administer via an infusion pump using a giving set with an in-line filter (15 micron).
  - At the end of each infusion, the bag, tubing and intravenous line should be visually inspected.
  - If for any reason the study drug is stopped (e.g. intravenous cannula change), treatment must be commenced as soon as possible and continued. In the event of the infusion being stopped for >15 minutes during the infusion or if more than 10% of the infusion is not administered, the reason should be recorded on the CRF.

Investigational Medicinal Product (IMP)

IMP dosage and treatment regime

- Providing the patient meets the inclusion criteria, they will be randomly assigned to either:
  - Arm 1: Standard care plus 1 g/kg 10% single dose mannitol infusion at 10ml/min
  - Arm 2: Standard care plus 1 g/kg 10% mannitol at 10ml/min followed by a second dose 1 g/kg repeated at 24 hours
  - Arm 3: Standard care alone

Participants randomised to Arm 2, to receive the second dose at 24 hours, will receive mannitol only if the serum osmolality is <320 mOsm/Kg and sodium <160 mEq/L

Calculated serum osmolality:

2 × (Na+) + Glucose + Urea (all in mmol/L)

https://www.mdcalc.com/calc/91/serum-osmolality-osmolarity

Weight (kg)	Dose (based on 1g/kg)	Volume and rate of Mannitol 10% solution (infuse at 10mL/min = 600mL/hour)
40	40g	400mL over 40mins
45	45g	450mL over 45mins
50	50g	500mL over 50mins
55	55g	550mL over 55mins
60	60g	600mL over 60mins
65	65g	650mL over 65mins
70	70g	700mL over 70mins
75	75g	750mL over 75mins
80	80g	800mL over 80mins
85	85g	850mL over 85mins
90	90g	900mL over 90mins
95	95g	950mL over 95mins
100	100g	1000mL over 100mins

*There is no formal guidance about dosing in extremes of bodyweight. Review risk / benefit with fluid balance and comorbidities. Infusion time can be extended if concerns re: fluid overload.

Investigational Medicinal Product (IMP)

Acute kidney injury (AKI) following mannitol administration

- Mannitol is known to exert pressure on the kidneys due to the effects of hyperosmolality and dehydration.
- Literature reports have been variable, but AKI has been quoted as occurring in between 10-20% patients following mannitol infusion.
- Independent risk factors may include older age, dose above 200g/day (not included in MACE-ICH) and hypertension with DBP>100mmHg.
- The patient cohort included in MACE-ICH may also be at risk of AKI and dehydration due to disease severity, inability to take oral fluids (‘nil by mouth’), infection and concomitant medicines.
- A transient drop in renal function (eg AKI stage 1) may be expected but if recognised early is usually reversible. Every effort should be made to minimise other nephrotoxic medicines (such as diuretics, NSAIDS, aminoglycosides, drugs affecting Renin-Angiotensin system) during treatment with mannitol, and to maintain careful fluid balance.
- Clinical judgement should be used in determining if any renal impairment observed is a minor transient change as part of a patient’s overall clinical picture or a more significant Adverse Reaction (AR) or Serious Adverse Event (SAE) depending on the degree of harm.

Safety reporting

Reporting timeframes

- All SAEs/SARs/SUSARs during infusion and post-treatment up to and including Day 28 will be collected.
- Fatal SAEs and safety outcome events (relating to thrombophlebitis; hyper/hyponatremia; pulmonary oedema; hypotension; renal impairment) will be reported up to and including Day 180
- All SAEs/SARs/SUSARs are reported using the following process:
  - Complete the 'Serious Adverse Event or outcome' CRF on the trial database
  - Completion of the above CRF will partially auto-populate the 'TAFR01912 Serious Adverse Event Reporting Form (CTIMP and Other)'. Please download and complete all remaining items on the form, then email to: RDSAE@nuh.nhs.uk (cc in mace-ich@nottingham.ac.uk)
  - Where event outcome is unknown at the time of the initial SAE report, please complete 'TAFR01911 SAE Follow-up Form' with updates, until resolution of the SAE. This form should be emailed to: RDSAE@nuh.nhs.uk (cc in mace-ich@nottingham.ac.uk)
  - Any SAE updates must also be reported on the trial database using the 'Data correction request' CRF
- After discharge, participants will be asked to contact the study site immediately in the event of a serious adverse event.
- Sites must inform the Coordinating Centre, Chief Investigator and Sponsor immediately (**within 24 hours**) of any serious adverse events, and the CI will review seriousness and causality in conjunction with any treating medical practitioners.
- Sites should record and monitor all adverse events until resolution, stabilisation or until it has been shown that the study treatment is not the cause.
- SAE forms must be signed off by the PI and filed in the site file

Safety Reporting

Identify and record Adverse Event (eCRF)

Assess for Seriousness, Causality, Severity & Expectedness by PI or appropriately qualified, delegated individual

Report SAE, SAR & SUSAR to Sponsor on *TAFR01912, SAE Reporting Form (CTIMP and Other)*

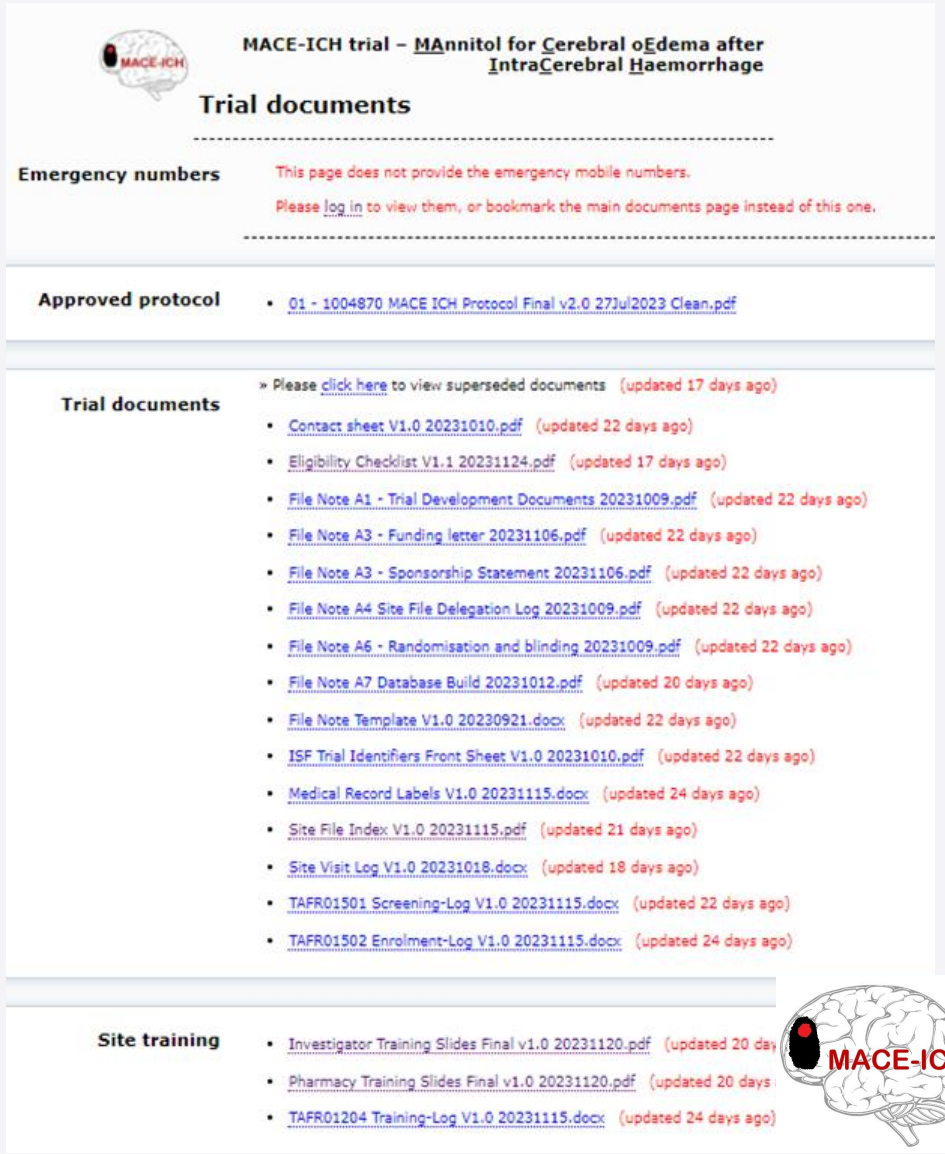
Where event outcome is unknown at time of SAE report, complete and submit *TAFR01911 SAE Follow-up Form* with updates, until resolution of the SAE

Any SAE updates after the initial eCRF completion must be reported on the database using the 'Data correction CRF'

MACE-ICH

Pharmacy Site File

- Please see the MACE-ICH documents page which can be accessed via the following link: https://stroke.nottingham.ac.uk/mace-ich/docs/
- The coordinating centre will not send hardcopy site files in the post for reasons of sustainability and version control. Sites are welcome to print and maintain a physical ISF if they prefer.
- The coordinating centre will send any amendment notifications electronically with guidance of if any documents need superseding, we will then put the updated documentation on the MACE-ICH website.
- Must be stored in a secure location and only accessible by the research team



MACE-ICH trial – MAnnitol for Cerebral oEdema after IntraCerebral Haemorrhage

Trial documents

Emergency numbers

This page does not provide the emergency mobile numbers.

Please log in to view them, or bookmark the main documents page instead of this one.

Approved protocol

- 01 - 1004870 MACE ICH Protocol Final v2.0 27Jul2023 Clean.pdf

Trial documents

» Please click here to view superseded documents (updated 17 days ago)

- Contact sheet V1.0 20231010.pdf (updated 22 days ago)
- Eligibility Checklist V1.1 20231124.pdf (updated 17 days ago)
- File Note A1 - Trial Development Documents 20231009.pdf (updated 22 days ago)
- File Note A3 - Funding letter 20231106.pdf (updated 22 days ago)
- File Note A3 - Sponsorship Statement 20231106.pdf (updated 22 days ago)
- File Note A4 Site File Delegation Log 20231009.pdf (updated 22 days ago)
- File Note A6 - Randomisation and blinding 20231009.pdf (updated 22 days ago)
- File Note A7 Database Build 20231012.pdf (updated 20 days ago)
- File Note Template V1.0 20230921.docx (updated 22 days ago)
- ISF Trial Identifiers Front Sheet V1.0 20231010.pdf (updated 22 days ago)
- Medical Record Labels V1.0 20231115.docx (updated 24 days ago)
- Site File Index V1.0 20231115.pdf (updated 21 days ago)
- Site Visit Log V1.0 20231018.docx (updated 18 days ago)
- TAFR01501 Screening-Log V1.0 20231115.docx (updated 22 days ago)
- TAFR01502 Enrolment-Log V1.0 20231115.docx (updated 24 days ago)

Site training

- Investigator Training Slides Final v1.0 20231120.pdf (updated 20 da
- Pharmacy Training Slides Final v1.0 20231120.pdf (updated 20 days
- TAFR01204 Training-Log V1.0 20231115.docx (updated 24 days ago)

MACE-ICH

Monitoring

Remote monitoring

- The trial coordinator will carry out the site monitoring visit remotely. A face-to-face visit may be triggered if there are ongoing concerns about a site despite remedies being suggested to resolve issues.
- The expectation is that sites will complete the monitoring documents, which will be signed off by the PI and returned to the Stroke Trials Unit. These documents include an ISF checklist and patient file checklists
- Sites will be notified of a sub-set of patients that have been randomly selected from the trial database to be monitored
- The completed monitoring documents will be reviewed by the trial coordinator and followed up with a report and action list

What next?

Before we issue green light and you can start recruiting:

- ✓ Signed training log after today's session
- ✓ CVs and GCPs for trial staff
- ✓ Signed contract
- ✓ Confirmation of C&C from R&D
- ✓ Staff to be authorised by PI on the online delegation log

Please can we remind you to add mace-ich@nottingham.ac.uk to your contacts list – not doing so may mean you miss important automated emails from our database (including randomisation and SAE alerts).

University of Nottingham
UK | CHINA | MALAYSIA

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NIHR | National Institute for Health and Care Research

NHS
Nottingham University Hospitals
NHS Trust

Thank you for listening
Any questions?

MACE-ICH

Email: mace-ich@nottingham.ac.uk

Website: https://stroke.nottingham.ac.uk/mace-ich/

Twitter: @MACE_ICH_Trial

Telephone: 0115 823 1770

Dr Kailash Krishnan
Chief Investigator

Di Havard
Senior Trial Manager

Solomon Adegbola
Follow Up Coordinator

Prof Philip Bath
Deputy Chief Investigator

Dr Jen Craig
Trial Manager

Sponsor: ResearchSponsor@nuh.nhs.uk

Emergency contact phone numbers:
Please log in to the MACE-ICH database to access

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