

Per-Participant Activities (2)

This tab should ONLY be completed for the second arm of studies

IRAS Reference Number:	0
Study Arm Name, Phase or other Designator (optional):	Control arm
Number of Participants in Arm 2	200

Area of Activity (select this first)	Specific Activity (Drop down only present when Area of Activity selected first - If required activity is not shown - follow guidance above)	Duration (Minutes)	Undertaken by (Required field - Drop down only)	Undertaken by (Optional field - free text)	Day - x to -y	Day 0	Column2	Column3	Column4	Column5	Column6	Column7	Column8	Column9	Column10	Column11	Column12
					Screen	Base	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 14	Day 30	Visit 10	Visit 11
Control																	
Participant Consent Procedures	Informed consent	30	Medical Staff		Service Support Cost												
Other Procedures or Activities	Medical history	15	Nursing/Manager		Treatment Cost												
Other Procedures or Activities	Prescription for study	10	Nursing/Manager		Research Cost												
Other Procedures or Activities	Concomitant medication check (on study)	15	Nursing/Manager		Treatment Cost												
Other Procedures or Activities	Randomisation (manual, IVRS or IWRS)	10	Nursing/Manager		Research Cost												
Other Procedures or Activities	CRF completion including data transfer and query resolution	30	Nursing/Manager		Research Cost												
Other Procedures or Activities	Review/monitoring of patient AEs/SAEs	15	Nursing/Manager		Research Cost	Research Cost	Research Cost	Research Cost	Research Cost	Research Cost	Research Cost	Research Cost	Research Cost	Research Cost	Research Cost	Research Cost	Research Cost
Non-Trial Cost	Telephone call	30	Nursing/Manager														
Interventions clinical	Weight & Height (including BMI if required)	20	Nursing/Manager		Treatment Cost												
Interventions clinical	Vital Signs measurements (Temp, BP, Pulse and respiration)	10	Nursing/Manager		Treatment Cost												
Interventions non-clinical	Subject Questionnaire	10	Nursing/Manager		Research Cost									Research Cost	Research Cost		

