

Risk of Aneurysm Rupture (ROAR) Study

Newsletter 3

Jul 2023

Welcome to ROAR

The ROAR Study has progressed well since the last Investigator Meeting in March on many fronts. We have presented at iSAH, received our first tranche of HES data ahead of time and seen a flurry of units opening for recruitment. Our focus right now is completion of baseline data collection this summer.

Data collection deadline - All baseline data collection is due to close 31st July 2023. Please have a final push to complete your datasets. If you think this isn't achievable then let us know ASAP and we can try to provide additional support.

Initial HES results - We are very excited to have received the first batch of HES data which arrived only 2 months after the application approval, and considerably less than the 6 months we were quoted. It is likely this was due to ROAR being selected for a trial of a new pathway for HES searches. We now have hospital admission and death data for 6,700 patients from the first 9 units who completed their data collection.

HES validation - We have used the HES data to validate the ROAR study design in the Southampton cohort. We found that HES identified all but one of SAH events that were known to the clinical team (39 of 40 events). We have gone on to verify all events not previously known to the team and identified via HES and found this identifies an additional 13 rupture events that would otherwise not be known showing the value of HES for this application. From this we estimate that HES and local records combined will identify 99.3% of all aneurysm ruptures that occur during follow-up comparing very favourably to conventional prospective cohort studies and validating the study design. We plan to write this up for publication in advance of the main ROAR study.

International Subarachnoid Haemorrhage Conference - The ROAR study and the above validation was presented at the 16th iSAH conference hosted by Duke University, USA with very positive feedback from amongst other members of the original ISUIA and PHASES study teams.

Rupture validation – Now we have tested the HES verification methodology we will work with one or two units to trial this externally over summer before a drive to verify rupture events in the 8 other units that now has HES results available in September.

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Site set up - We are pleased to say that St Georges, Imperial, Preston, Birmingham and Romford have all opened since the last newsletter.

	Data collection complete	
	Southampton	1,590
	Manchester	1,472
	Leeds	804
	Plymouth	610
	Bart's	604
	Cardiff	528
	Bristol	521
	Stoke	429
ě	Middlesbrough	401
	Romford	303
1	Cambridge	157
ı	Total	7,419
	Set up and collecting data	
3	King's	1,229
	Queen Square	890
	Liverpool	608
	Birmingham	500
	Hull	500
,	Brighton	446
k	St George's	400
9	Nottingham	336
	Imperial	222
	Preston	210
	Sheffield	176
	Oxford	20
	Total	5,539
	In set up	
	Dundee	N/A
L	Edinburgh	N/A
٩	Glasgow	N/A
1	Newcastle	N/A











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<u>Timeline of events</u>

Data collection/verification		<u>National Databases</u>
	Oct 2022	Pilot HES search application 🗸
Pilot case verification – all ruptures will undergo verification of data accuracy by a senior team member (i.e. PI/SpR). This can begin using the known ruptures from local data	Dec 2022	Pilot HES search approval – the pilot search will use the patients identified so far (approximately 10,000) and link them to the HES database. This will allow early data cleaning and fault finding for the final search
Complete R&D set ups	Mar 2023	
	Apr 2023	Pilot HES data released 🗸
	May 2023	
	Jun 2023	Full HES search application 🗸
Complete baseline data collection Pilot cases from first HES search released to units for verification of potential rupture event	Jul 2023	
	Aug 2023	Full HES search approval
	Dec 2023	Full HES data released
Full list of cases for verification	Jan 2024	
Complete case verification	Apr 2024	
Initial study results	Aug 2024	

^{**}Items in blue apply only to units set up and with eligible patient data available to be included in the pilot search.







