The ROMBO Study NEWSLETTER ISSUE: 5 Autumn/Winter 2019

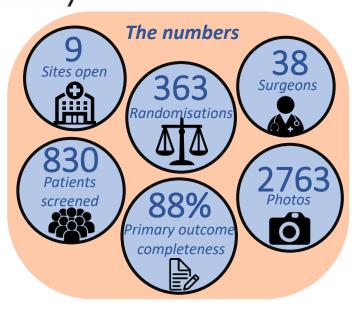
A message from the CI:



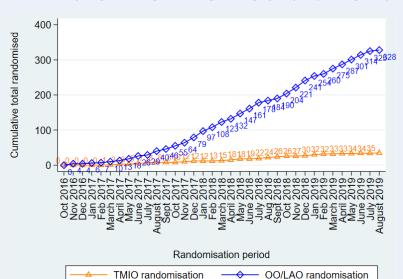
Welcome to this Autumn/Winter's newsletter. We have done it!! We have finished the recruitment phase of the study. Well done to everyone for your hard work. Obviously there

is still much to do in following up the patients and with collecting and analysing the data. It does feel however, that the end is now in sight. We hope you enjoy this newsletter and look forward to seeing you all in the new year to discuss the results.

Paul Barham, Chief Investigator



End of ROMIO Recruitment - the final numbers



00 vs. LAO 328 +TMIO 35*
* Bristol, Bath and Southampton

Site	No. randomised	Av no. randomised per month
Plymouth	88	2.8
Nottingham	63	2.4
Bristol	55	1.6
Leicester	46	1.5
Southampton	37	1.3
Preston	24	0.9
Edinburgh	19	0.8
Bath	15	0.5
Salford	14	0.7





Follow-ups

Follow-ups will continue until August 2021.

We are following all patients until 24 months. Some patients will also have a 36 month followup. NB - at 36 months, only the yellow questionnaire booklet is sent (NOT the resource use diary/call).

See page 23 of the protocol for further guidance.

Investigator results meeting April 2020

We are planning an investigator meeting in April 2020 to discuss the first set of ROMIO results. A doodle poll will soon be circulated – please select your availability when you receive it.



o ooooooooo Data cleaning o oooooooooo

Please ensure all your data is in the database and query-free ('clean') by 22nd Nov 2019. We need a clean dataset to analyse to be able to tell you the first set of results for ROMIO. We are planning to initially report the data for patients up to 90d post-surgery (including primary outcome data). A second paper will report the data up to 24/36 months.

Image Assessments

We have been busy creating an online platform to facilitate the assessment of nearly 2000 intra-operative images selected for clinical assessment. The electronic platform has been designed to work on mobile devices as well as desktop computers to ensure the ROMIO assessors can review images at their convenience.



We've recruited 12 images assessors, 7 of these volunteers are external to the study and have kindly offered their services after our Twitter call out. Patients' images have been randomly allocated amongst these individuals to ensure inter-rater reliability. We have tried to remove all procedural identifiers from the abdominal phase images, so that assessors are uncertain whether the operation was LAO or OO. We're looking forward to presenting the results of the image assessments in December.

Planned PPI

In Jan 2020 we will hold a meeting with patients in Nottingham to find out:

- What they want to know about the **ROMIO** results
- How they would like to be provided with the information.

ROMIO word search

1. ROMIO

5 OPFN

2. SURGERY

3. OESOPHAGUS

4. LAPAROSCOPE

J.	O.	_,	v
6.	CRI	F	
7.	DA	TΑ	

8. SITE

E	Р	0	С	S	0	R	Α	Р	Α	L
R	0	Р	E	N	Н	N	K	Z	1	E
Α	P	E	1	О	Е	С	F	R	D	М
X	Е	Т	S	U	G	R	0	Υ	U	Α
S	Υ	Α	R	О	E	F	М	1	0	Т
U	S	1	G	E	Р	Α	Т	Α	Т	Α
R	Α	S	E	R	1	н	0	S	E	D
G	Z	1	Т	М	С	1	Α	T	С	Т
E	S	0	Α	R	М	E	P	G	Α	R
R	Α	В	1	0	S	T	1	E	U	Х
Υ	Е	L	R	E	Α	G	E	T	1	S









