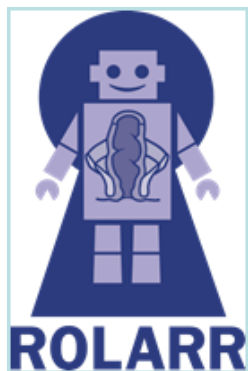


Key Trial & Data Management Considerations for Planning Surgical Trials

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RObotic versus LAparoscopic Resection for Rectal Cancer

- Randomised
- Same operation carried out in two different ways
- International

GLiSter



Next Generation intraoperative Lymph node staging
for Stratified colon n cancer surgery

- Exploratory dose-finding study
- CTIMP
- International



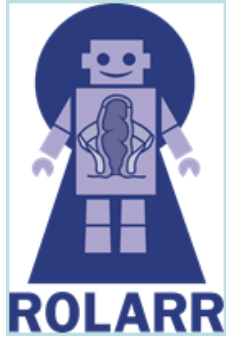
Sacral nerve stimulation versus the FENIX_{TM} magnetic sphincter augmentation for adult faecal incontinence: a Randomised Investigation

- Randomised
- Two CE marked devices
- Two different operations



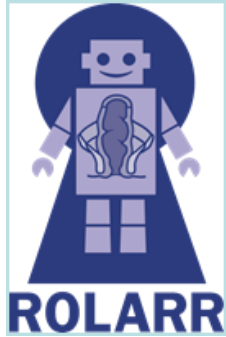
Liver Resection Surgery Versus Thermal Ablation for Colorectal LiVer MetAstases

- Randomised
- Surgery versus ablation
- International



Protocol
Adverse Events
Learning Curve
Data Collection





Protocol
Adverse Events
Learning Curve
Data Collection



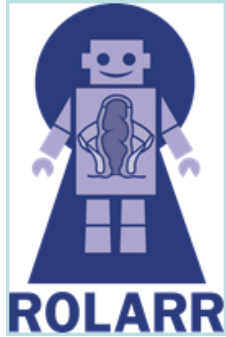
Protocol

Our protocols were pragmatic i.e. designed to reflect standard practice as much as possible:

- Trial assessments
- Non-prescriptive

Key Considerations:

- Timing of consent, randomisation and treatment
- How flexible can the treatment definitions be?



Protocol
Adverse Events
Learning Curve
Data Collection



Adverse Events

Definition: Any untoward medical event in a participant

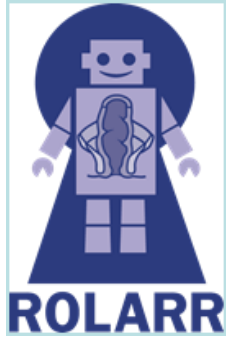
Adverse events termed **complications** in our protocols

Issues

- Interpretation of definitions
- Concern from surgeons that this was sensitive information

Key Considerations:

- Working definition of complications
- Classification of complications
- Monitoring of complications



Protocol
Adverse Events
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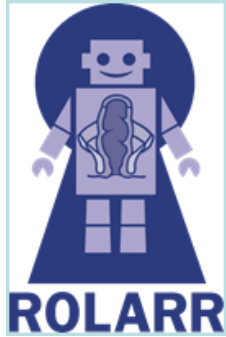


Learning Curve

Issue: Recognised effect in surgical trials that can introduce bias into a trial

Key Considerations:

- Establish a minimum baseline level of experience
- Can this be easily gained?
- Ongoing collection of procedure experience
 - Frequency
 - Detail required



Protocol
Adverse Events
Learning Curve
Data Collection



Data Collection

Issue: Need for upfront descriptions of each operative procedure and stages of the operation.

Considerations:

- Clear definitions for each stage of the operation
- Clear definitions for surgical endpoints
- Guidance/standardised assessment processes where required

Theatre Procedure and Timings

Please use 24 hr clock

Time into anaesthetic room

Hours	:	Minutes
	:	

Time of wound closure completion

Hours	:	Minutes
	:	

Time of first incision

Hours	:	Minutes
	:	

Time patient left theatre

Hours	:	Minutes
	:	

Was there a laparoscopic part of the operation? Yes No

If yes: Total duration of laparoscopic surgery*

--	--	--

 min

Was there more than one episode of laparoscopic surgery during the operation? Yes No

**Total duration of laparoscopic surgery is defined as from the creation of pneumoperitoneum to the completion of laparoscopic mobilisation. It does not include the use of laparoscopy for formation of anastomosis or creation of ileostomy.*

Was there a robotic part of the operation? Yes No

If yes: Total duration of robotic surgery**

--	--	--

 min

Was there more than one episode of robotic surgery during the operation? Yes No

***Total duration of robotic surgery is defined as the total time that the robot is docked to the patient.*

Which system was used?
(tick one only)

da Vinci™ standard
 da Vinci™ S
 da Vinci™ Si

Total number of robotic arms used

--

Was there a conversion to open?* Yes No

If yes: Stage Immediately (*at start*) Abdominal dissection Pelvic dissection

Reason Operative difficulty,
describe:

--

Operative complication (*Please record details on pages 8 and 9*)

Robotic malfunction/
complication,
describe:

--

Other, describe

--

**An intraoperative conversion to open is defined as the use of a laparotomy wound for any part of the dissection. The use of a limited laparotomy wound to facilitate a low staples anastomosis and/or specimen extraction is permissible and not defined as an open conversion.*

Completed by

--

Date

Day	Month	Year

Form continues
on next page ►

Thank you!