ISRCTN04149919 https://doi.org/10.1186/ISRCTN04149919

Randomised Controlled Trial (RCT) comparing two methods of repairing external anal sphincter lacerations

Submission date
01/09/2005

Recruitment status
No longer recruiting

Registration date
01/09/2005

Overall study status
Completed

Last Edited
10/09/2012

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MCT-41547

Study information

Scientific Title

Study objectives
When overlapping surgical repair of third and fourth degree obstetrical lacerations of the external anal sphincter is compared to the standard end-to-end method, it will result in superior symptomatic, anatomical and functional outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from IWK Health Centre Research Ethics Board on the 15th April 2005.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Third or Fourth degree tear of the External Anal Sphincter (EAS) at childbirth.

Interventions
Two arms:
1. Traditional end-to-end repair of the EAS
2. Overlapping repair of the EAS

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Rate of flatal incontinence at 6 months post repair.

Key secondary outcome(s)
1. Rate of fecal incontinence at 6 months post repair
2. Integrity of EAS by endoanal ultrasound
3. Function of EAS by anal manometry
4. Quality of life by validated QOL measure
5. Post-operative complications

Completion date
30/09/2003

Eligibility

Key inclusion criteria
1. Complete third or fourth degree tear of the External Anal Sphincter
2. Aged 18 - 49 years old, female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Previous 3rd or 4th degree tear
2. Significant history of anal incontinence
3. Inflammatory bowel disease or other gastrointestinal condition which might affect functional outcome

Date of first enrolment
01/10/2000

Date of final enrolment
30/09/2003

Locations

Countries of recruitment
Canada

Study participating centre
IWK Health Center
Halifax, Nova Scotia
Canada
B3J 3G9

Sponsor information

Organisation

Dalhousie University (Nova Scotia) (Canada)

ROR
https://ror.org/01e6qks80

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-41547)

Funder Name
Nova Scotia Health Research Foundation (Canada)

Alternative Name(s)
NSHRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Funder Name
Dalhousie Medical Research Foundation (Canada)

Funder Name
The Atlee Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2010		Yes	No
Results article	results	01/10/2012		Yes	No