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

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

Submission date	Recruitment status	[ ] Prospectively registered
01/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/09/2012	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

Rate of flatal incontinence at 6 months post repair.

Secondary outcome measures
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

Overall study start date
01/10/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
150

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)

Sponsor details
1236 Henry Street
Halifax, Nova Scotia
Canada
B3H 3J5

Sponsor type
University/education

Website
http://www.dal.ca/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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