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# 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 |