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Recognition and expertise in the prevention of anal incontinence from ruptured sphincter

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2017	Urological and Genital Diseases	[_] Record updated in last year

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
N0158108052

Study information

Scientific Title
The REPAIR study - Recognition and Expertise in the Prevention of Anal Incontinence from Ruptured Sphincter: a randomised controlled trial

Acronym
REPAIR

Study objectives
Which method of surgical repair for 3rd and 4th degree obstetric anal sphincter injury results in the better outcome (the overlap method or the juxtaposition method), in terms of the incidence of anal incontinence at 12 months postpartum?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urological and Genital Diseases: Anal incontinence

Interventions
The proposed trial is a conventional randomised controlled trial of surgical method in the management of an infrequent complication of childbirth that nevertheless blights the lives of many thousands of women in the UK, and more worldwide. The team also hope to be able to draw conclusions about the impact on outcome that arises from the individual skill of the clinician undertaking the repair.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Anal incontinence at 1 year after repair

Key secondary outcome(s))
Quality of life 1 year after repair

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. All women with complete obstetric anal sphincter rupture (3rd or 4th degree perineal tear)
2. Informed consent is given
3. Authorised clinician available to perform or supervise the repair

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
Female

Key exclusion criteria
1. Previous surgery for obstetric repair or anal fistula
2. Refuse or withdraw consent

Date of first enrolment
01/10/2002

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Charity

Funder Name
North Staffordshire Medical Institute

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes