

Sitz bath for acute anal pain: cold or warm?

Submission date 27/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/01/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/06/2010	Condition category Digestive System	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
001

Study information

Scientific Title

Sitz bath for acute anal pain: cold or warm? A randomised controlled trial

Acronym

FRI.CA study

Study objectives

A warm sitz bath is better than a cold one to relieve acute anal pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics board on the 2nd February 2006 (ref: 2005/2203/l)

Study design

Randomised controlled, two-arm trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Acute anal pain from haemorrhoids or anal fissure

Interventions

Treatment with sitz bath every 12 hours during 7 days. Follow-up will be performed every day during the first 7 days of the study. Recommendations of temperature for sitz bath, diary record of temperature and pain (Visual Analogue Scale [VAS]) will be assessed.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Pain control, evaluated using the VAS during the first 7 days of the study.

Secondary outcome measures

Outcome of disease (haemorrhoids or fissure), measured during the first 7 days of the study.

Overall study start date

01/01/2007

Completion date

31/12/2008

Eligibility**Key inclusion criteria**

1. Adult patients aged over 18 years, either sex
2. Acute anal pain for haemorrhoids or anal fissure
3. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. No acceptance
2. Previous anal surgery

Date of first enrolment

01/01/2007

Date of final enrolment

31/12/2008

Locations**Countries of recruitment**

Spain

Study participating centre

Hospital del Mar
Barcelona
Spain
08003

Sponsor information

Organisation

Hospital del Mar (Spain)

Sponsor details

Passeig Maritim 25 - 29
Barcelona
Spain
08003

Sponsor type

Hospital/treatment centre

Website

<http://www.hospitaldelmar.cat/>

ROR

<https://ror.org/03a8gac78>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital del Mar (Spain)

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	01/08/2010		Yes	No