Sitz bath for acute anal pain: cold or warm?

Submission date Prospectively registered Recruitment status 27/11/2008 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 02/01/2009 Completed [X] Results [] Individual participant data Last Edited Condition category 29/06/2010 **Digestive System**

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr David Parés

Contact details

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Additional identifiers

Protocol serial number

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/I)

Study design

Randomised controlled, two-arm trial

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

https://ror.org/03a8gac78

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital del Mar (Spain)

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	d Peer reviewed	? Patient-facing?
Results article	results	01/08/2010	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	5 No	Yes