

# Sitz bath for acute anal pain: cold or warm?

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr David Parés

### Contact details

Hospital del Mar  
Colorectal Surgery Unit  
Passeig marítim 25 - 29  
Barcelona  
Spain  
08003

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/08/2010   |            | Yes            | No              |