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The use of perianal methylene blue injection on post-haemorrhoidectomy pain

Submission date
04/12/2010

Recruitment status
No longer recruiting

Registration date
11/07/2011

Overall study status
Completed

Last Edited
16/09/2016

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Haemorrhoids, also known as piles, are swellings containing enlarged blood vessels that are found inside or around the bottom (the rectum and anus). Surgery to remove haemorrhoids (haemorrhoidectomy) often leads to pain and discomfort in the period after the operation. Injection of methylene blue, a biological dye, around the anus (perianal) has been shown anecdotally to cause less pain. Methylene blue has also been used successfully in patients with severe itch around the anus who failed to improve with medication. Excellent results have been reported in an earlier study of patients undergoing lateral sphincterotomy (a procedure to treat anal fissures). The aim of this study is to assess the effectiveness of methylene blue injection on pain after haemorrhoidectomy.

Who can participate?
Patients aged between 21 and 80 with haemorrhoids

What does the study involve?
Participants are randomly allocated to be treated with either methylene blue and marcaine (an anesthetic), or marcaine only. After the operation participants are asked to fill in a pain diary and to attend the standard routine reviews in the outpatient clinics. Participation in the study lasts 6 weeks, which is the usual follow-up period for a haemorrhoidectomy patient. Participants need to visit the doctor’s office two times in the course of the study at 2 weeks and 6 weeks after the procedure for assessment of their wounds. These visits are part of routine assessment after surgery.

What are the possible benefits and risks of participating?
There is no expected benefit from participation in this study. However, participation in this study may add to the medical knowledge about the use of methylene blue on pain after haemorrhoidectomy. Methylene blue, being a biological dye, will cause temporary discoloration of the skin and urine. Very rarely, perianal infections may occur. Allergic reactions can occur with any drug. Common symptoms include rash and itch. To date, no severe or life-threatening allergic reaction has occurred with methylene blue. Symptoms of a severe reaction include:

swelling of the face, difficulty breathing, and a sudden drop in blood pressure that may cause dizziness. Even though methylene blue is commonly used, participants may experience other side effects that have not yet been reported.

Where is the study run from?
Khoo Teck Puat Hospital (Singapore)

When is the study starting and how long is it expected to run for?
August 2008 to January 2012

Who is funding the study?
Investigator initiated and funded (Singapore)

Who is the main contact?
Dr Tan Kok Yang

Contact information

Type(s)
Scientific

Contact name
Dr Tan Kok Yang

Contact details
Khoo Teck Puat Hospital
90 Yishun Central
-
Singapore
768828

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SUR-001, DSRB Ref: D/07/508

Study information

Scientific Title
A single centre prospective randomised clinical trial of the use of perianal methylene blue injection on post-haemorrhoidectomy pain

Study objectives

To assess the efficacy of perianal methylene blue injection in the reduction of post-haemorrhoidectomy pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Healthcare Group Domain - Specific Review Board (DSRB), 27/03/2008, ref: D/07/508

Study design
Single-centre prospective randomised controlled 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Symptomatic 3rd and 4th degree haemorrhoids

Interventions
Patients will be randomised to undergo haemorrhoidectomy with methylene blue and marcaine 0.5% or marcaine 0.5% only alone intradermal injections using sealed envelopes. A standard medication package will be given to all patients post-operatively.

A standardised general anaesthesia technique would be used. All patients will be given fleet enema prior to surgery. A colorectal surgeon will perform standard Milligan Morgan open haemorrhoidectiomies. 4ml of 1% methylene blue and 16ml of 0.5% marciane will be injected into perianal skin if patient is randomised into methylene blue group. 16mls of marcaine 0.5% and 4ml of saline will be infected if randomised to marcaine alone arm.

Post operative care:
All patients will be prescribed with Fybogel® one sachet daily, Daflon® two tablets twice per day, paracetamol 1g six hourly and diclofenac 50mg twice a day for 2 weeks. All patients will be discharged on the same post-operative day unless otherwise indicated. Wound care advice will be given for patients to clean their wound with shower spray twice per day. They will be given appointment for follow up at 2 weeks and 6 weeks post surgery.

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylene blue, marcain

Primary outcome measure
1. Pain, assessed using a 11-point visual analogue pain score from 0 to 10 (0 = no pain; 10 = unbearable pain). Participants will be asked to record their maximum pain score daily before retiring.
2. Total number of analgesics tablets patients have taken for the day

Secondary outcome measures
Complications which include:
1. Pain requiring unscheduled stay or unscheduled return
2. Urinary retention
3. Delayed bleeding
4. Discharge
5. Itching
6. Skin reaction to methylene blue

Overall study start date
27/08/2008

Completion date
26/01/2012

Eligibility

Key inclusion criteria
1. Fresh cases of symptomatic 3rd and 4th degree haemorrhoids
2. Aged between 21 and 80 years of age
3. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria

1. Undergoing combined procedures for fissures or fistulae
2. Do not give informed consent
3. Allergy reactions to diclofenac, Daflon®, Fybogel®, methylene blue, paracetamol
4. Pregnant or breast feeding women

Date of first enrolment
27/08/2008

Date of final enrolment
26/01/2012

Locations

Countries of recruitment
Singapore

Study participating centre
Khoo Teck Puat Hospital
-
Singapore
768828

Sponsor information

Organisation
Khoo Teck Puat Hospital (Singapore)

Sponsor details
90 Yishun Central
-
Singapore
768828

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05wc95s05

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded (Singapore)

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