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Lidocaine patch application in painful surgical scars

Submission date	Recruitment status	[_] Prospectively registered
08/11/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/11/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/12/2022	Surgery	

Plain English summary of protocol

Background and study aims
Chronic (long-term) pain after surgery is a frequent complaint in orthopedic practice. Drug and non-drug treatments have been proposed for this condition. Recently, a lidocaine (local anesthetic) patch has been developed. The aim of this study is to test this plaster as a method of treatment for pain after orthopedic surgery in comparison to therapeutic massage performed on the incision.

Who can participate?
Patients between 13 and 70 years old who underwent foot and ankle surgery and experience pain at least 3 months later

What does the study involve?
Patients are randomly allocated to one of two groups. One group apply the lidocaine patch for 12 hours a day for 3 months. The other group perform manual manoeuvres over the scar for 10 minutes each, 3 times a day, over 3 months. Pain, satisfaction with the surgery and quality of life are assessed at the start of treatment and after 30, 60 and 90 days.

What are the possible benefits and risks of participating?
Participants could benefit from pain relief and improved quality of life. The risks include drug hypersensitivity and overdose.

Where is the study run from?
Hospital Ipiranga (Brazil)

When is the study starting and how long is it expected to run for?
December 2016 to September 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Joao Paulo Gonçalves dos Santos
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
64900217.0.0000.5488

Study information

Scientific Title
Lidocaine 5% patch application in painful surgical scars: a randomised controlled trial

Study objectives
The lidocaine 5% patch is a useful tool for relieving post-operatory pain in patients who underwent foot and ankle surgeries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics in Research Committee at Hospital Ipiranga - State Secretary of Health in São Paulo State, Brazil, 08/03/2017, ref: 1.953.666

Study design
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
Post-operative pain

Interventions
Patients are randomised using random.org to either:
1. Application of lidocaine 5% patch for 12 hours/day for 3 months
2. Manual maneuvers over the scar for 10 minutes each, 3 times a day, over 3 months

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain, measured with the visual analogue scale (VAS) at baseline and 30, 60 and 90 days of follow-up

Secondary outcome measures
Measured at baseline and 30, 60 and 90 days of follow-up:
1. Satisfaction with surgery, measured with the personal satisfaction index
2. Quality of life, measured with the SF-36 questionnaire

Overall study start date
01/12/2016

Completion date
22/09/2017

Eligibility

Key inclusion criteria

1. Patients between 13 and 70 years old
2. Underwent foot and ankle surgery at Hospital Ipiranga between January 2015 and February 2017
3. Sustained post-operative pain at least 3 months after the procedure

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
37

Key exclusion criteria
1. Patients younger than 13 and older than 70 years old
2. Allergics to lidocaine
3. Skin lesions or illness
4. Non-union or malunion
5. Infection
6. Patients who abandon follow-up

Date of first enrolment
01/04/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
Brazil

Study participating centre
Hospital Ipiranga
Avenida Nazaré, 28 - Ipiranga
São Paulo
Brazil
04262-000

Sponsor information

Organisation
Hospital Ipiranga

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication in Acta Ortopedica Brasileira, a Brazilian orthopedic journal.

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from João Paulo Gonçalves dos Santos (jpgdsantos@gmail.com) or Rafael da Rocha Macedo (rrochamacedo@yahoo.com.br).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/10/2021	01/12/2022	Yes	No