ISRCTN13166883 https://doi.org/10.1186/ISRCTN13166883

Pain relief effect of angiopuncture therapy on patients with postoperative pain

Submission date
01/05/2023

Recruitment status
No longer recruiting

Registration date
18/05/2023

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
There are different ways to use needles for therapeutic purposes. Dry needling, traditional acupuncture, and western medical acupuncture all involve putting thin needles into the skin. However, they have some differences in their indications and techniques.

Traditional acupuncture and western medical acupuncture can be used for a wider range of health issues, including problems with muscles and bones, digestion, and nerves. Dry needling, on the other hand, is specifically used to treat pain related to muscles and bones. Acupuncture focuses on specific points on the body, while dry needling targets trigger points.

There are other ways to alleviate pain, such as nerve blocks, oral medications, and injections. However, this article talks about a new technique called angiopuncture therapy, which involves making small holes in the skin with needles to reduce pain in patients after surgery. The goal of the study was to see if this technique could help patients feel better.

Who can participate?
Patients aged 20-65 years with acute foot and ankle trauma and pain after foot and ankle surgery.

What does the study involve?
Doctors used a handheld ultrasound machine to find 3-4 blood vessels near the injured area. Then, they used a small needle (0.18mm wide and 25mm long) to poke into those blood vessels for about 15 minutes. They checked the patient's pain level and heart rate before and after the acupuncture to see if it helped with their pain. The procedure was carried out on the first and second day after surgery.

What are the possible benefits and risks of participating?
The potential benefit is pain relief.
The potential risk is being more painful.

Where is the study run from?
Gaomi People's Hospital (China)

When is the study starting and how long is it expected to run for?
June 2021 to June 2022

Who is funding the study?
This study was supported by Health Evaluation and Intervention Using Advanced Raymedy System of Raymedy Bio-Energy InnoTech Limited (CityU ref.: 9239056) and JanusLean Biotech Company Limited (HKTech 300' programme of City University of Hong Kong)

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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
9239056

Study information

Scientific Title
Angiopuncture: a novel treatment for pain relief

Study objectives
Angiopuncture therapy approach could assist with pain relief in individuals with postoperative pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2021, Research ethics committee of Gaomi People's Hospital (Gaomi City People's Hospital, No. 77 Zhenfu Street (West), Gaomi City, Shandong Province, China; +86 536-2323273; gyrlzy2009@163.com), ref: GYLL2022-02

Study design
Interventional non randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Angiopuncture on patients with postoperative pain

Interventions
Physicians used handheld ultrasound Doppler to measure 3-4 perforators at the proximal end of the trauma site, and then puncture the perforators with a filiform needle (size: 0.18mm gauge * 25mm length) for 15 minutes, and finally monitor the patient's pain score and heart rate data before and after acupuncture.

Doppler probes were used to locate cutaneous perforator and angiopuncture therapy was carried out from the 1st day to the 2nd day after surgery. The Numerical Rating Scale (NRS) was used to evaluate the degree of pain before and after puncture.

Duration of therapy is 20 mins each day until 72h.

Intervention Type
Other

Primary outcome measure
Pain is measured using the numeric rating scale (NRS) at baseline, 6, 12, 24, 36, 48, 60 and 72 hours

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2021

Completion date
04/06/2022

Eligibility

Key inclusion criteria
Patients aged 20-65 years with acute foot and ankle trauma and pain after foot and ankle surgery.

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
41

Total final enrolment
41

Key exclusion criteria
1. Have scars and deformities on the lower extremity surface
2. Cannot cooperate with the locating method of acupuncture
3. Allergy to any material
4. Pregnant or breastfeeding women

Date of first enrolment
01/01/2022

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
China

Study participating centre
Gaomi People's Hospital
No. 77 Zhenfu Street (West)
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Sponsor information

Organisation
City University of Hong Kong

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/03q8dnn23

Funder(s)

Funder type
Industry

Funder Name
Raymedy Bio-Energy InnoTech Limited

Funder Name
JanusLean Biotech Company Limited (HKTech 300' programme of City University of Hong Kong)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are available upon request form HAN Rong, ronghan5-c@my.cityu.edu.hk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset			03/05/2023	No	No
Dataset			03/05/2023	No	No
Results article		12/01/2024	10/06/2024	Yes	No