The BFF trial: "The Better to Fix or Fuse study"

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint injuries
Study type	Interventional

Summary

ID

NL-OMON52717

Source
ToetsingOnline

Brief title
The BFF study

Condition

- Bone and joint injuries
- Fractures
- Bone and joint therapeutic procedures

Synonym
Lisfranc fracture, midfoot fracture

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: arthrodesis, Foot, internal fixation, Lisfranc

Outcome measures

Primary outcome

Primary outcome parameters: quality of life

Secondary outcome

Secondary outcomes: Complications, functional outcomes, gait analysis and cost

effectiveness.

Study description

Background summary

The Lisfranc injury is a complex injury of the midfoot. It can result in persistent pain and functional impairment if treated inappropriately. In Lisfranc fracture dislocation treatment options are primary arthrodesis of the midfoot joints or open reduction and internal fixation with retaining of the midfoot joints. There is no gold standard for the treatment of these Lisfranc injuries as described in literature.

We hypothesize that patients will have a better quality of life and less complications during follow-up when undergoing a primary arthrodesis for unstable fracture dislocations in the Lisfranc midfoot joints compared to open reduction and internal fixation. Further, we expect this approach to be more cost effective than the operative stabilization with retaining of the dislocated joints, as patients will be exposed to reduced number of reinterventions and hospital stay and/or prolonged use of pain medication, without compromising functional outcome and gait.

Study objective

The aim of the proposed study is to define optimal treatment for the Lisfranc fracture dislocation, either primary arthrodesis or open reduction and internal fixation, in regard to quality of life, complications, functional outcomes and cost effectiveness. We hypothesize that patients will have a better quality of life and less complications during follow-up when undergoing a primary arthrodesis for unstable fracture dislocations in the Lisfranc midfoot joints

compared to open reduction and internal fixation. Further, we expect this approach to be more cost effective than the operative stabilization with retaining the dislocated joints, as patients will be exposed to reduced number of reinterventions and hospital stay and/or prolonged use of pain medication, without compromising functional outcome and gait.

Study design

An open (non-blinded) prospective randomized controlled clinical trial.

Intervention

Patients with Lisfranc fracture dislocation will be randomly allocated to treatment with either primary arthrodesis or open reduction and internal fixation.

Study burden and risks

The expectations of this study are that operative treatment is beneficial for the patient with a unstable Lisfranc injury. The risk of specific complications is low and generally similar in both operative treatment modalities. Primary arthrodesis is expected to have improved results in functional scoring systems with less secondary surgical procedures compared with open reduction and internal fixation. Literature indicates that both treatment options from the study are accepted for Lisfranc fracture dislocation. No clear advantage for one treatment option is found at present in the literature.
The burden of the study seems to be not much higher compared to standard treatment, because follow-up is standardized according to current trauma guidelines. The radiation exposure will not be different from standard of care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Aged >=18 years
- Acute Lisfranc fracture injury (< 6 weeks after trauma)
- Displaced or unstable with weight bearing radiographs
- Independent for activities of daily living (yes/no question)
- Informed consent

Exclusion criteria

- Aged <18 or years
- Open Lisfranc injury
- Pure ligamentous Lisfranc injury
- Non-displaced and stable with weight bearing radiographs
- Contra-indications for general or locoregional anaesthetic techniques
- Other fractures at the ipsilateral leg
- Pre-existent abnormalities at the Lisfranc complex
- Pre-existent immobility

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-06-2020
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	08-05-2020
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	19-01-2021
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-01-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL73038.096.20