3D Virtual Surgery In an Orthopaedic-trauma Network (3D ViSION trial) A randomised-controlled study initiated by the department of Trauma Surgery, Orthopaedic Surgery and the 3D lab of the University Medical Center Groningen

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To assess the following research questions: 1. Does the use of 3D virtual preoperative planning of surgery improve functional outcome as measured by Patient-Reported Outcome in comparison to conventional surgery (using conventional radiographs and/…

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

Summary

ID

NL-OMON51389

Source
ToetsingOnline

Brief title
3D ViSION trial

Condition

- Bone and joint injuries
- Bone and joint therapeutic procedures

Synonym

ankle and wrist; bone fractures involving the joint, intra-articular fractures of the knee

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3D virtuele surgery, Intra-articular fractures, pre-operative planning

Outcome measures

Primary outcome

1. The primary endpoint is patient-reported outcome, which will be assessed

with validated follow-up questionnaires.

Secondary outcome

2. The secondary endpoint is the residual fracture displacement (gap and

step-off in mm), as measured on the postoperative CT-scan.

3. The tertiary endpoint is operation efficiency in terms of operation time

(minutes), blood loss (mL) and radiation exposure (mGym2).

4. The last endpoint is the cost effectiveness.

Study description

Background summary

In surgical treatment of intra-articular fractures, achieving an optimal anatomical reconstruction improves the functional outcome. These fractures often consist of complex fracture patterns with multiple fragments displaced in different directions, and are considered among the most complicated fractures to treat. Currently, the surgical strategy is based on conventional imaging methods such as plain radiographs and/or a 2D CT scan. However, 2D assessments of these complex multi-directional fractures are known to be highly user

dependent and tend to underestimate the displacement. 3D visualizations of the fracture might provide the surgeon with a better understanding of the fracture. Pre-operative 3D virtual planning could therefore help to improve the surgical outcome in terms of quality of the fracture reduction and reduce operation time, blood loss and radiation exposure.

Study objective

To assess the following research questions:
1. Does the use of 3D virtual preoperative planning of surgery improve functional outcome as measured by Patient-Reported Outcome in comparison to conventional surgery (using conventional radiographs and/or 2D CT images)?
2. Does the use of 3D virtual planning of the surgery improve fracture reduction?
3. Does the use of 3D virtual planning of surgery increase operative efficiency in terms of operation time, blood loss and radiation exposure?
4. What is the cost effectiveness of 3D assisted surgery?

Study design

All patients who will be included in this Randomized Controlled trial will be operated for an intra-articular fracture of the wrist, knee or ankle and randomized between preoperative planning with conventional imaging (control group) or a 3D virtual fracture model (intervention group).

Intervention

In the intervention group, surgery will be prepared by using a 3D virtual fracture model (based on the CT images) in addition to conventional imaging. In the control group the preoperative planning will be performed by using conventional imaging (i.e. radiographs and/or 2D CT images) according to the standard of care.

Study burden and risks

The extent of burden and risks for patients participating in the study is considered low, because the operative procedure itself will not change. The surgery and follow-up will be performed according to the standard of care. The only addition is that in the intervention group surgery will be prepared by using a virtual 3D model of the fracture as an addition to the conventional images. The operative procedure itself won*t change. With the outcome of this study, we intend to present the results at international conferences and publish them in international peer-reviewed journals.

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

- Acute fractures (<3 weeks after the initial injury)
- Fracture of one of the following body regions (distal Radius, proximal Tibia, distal Tibia/Ankle, see table below for specific fracture types that are eligible for inclusion)
- Operative treatment
- Availability of a diagnostic (Pre-operative) CT-Scan available (Slice thickness <= 1 mm)
- Age >= 18 years
- Understanding of the Dutch language

Table: Fracture types which are eligible for inclusion.
Nr Fracture Location AO classification

1 Radius Distal 2R3B; 2R3C
2 Tibia Proximal 41B; 41 C
3 Tibia/Ankle Distal 43B; 43C / 44B/C with tertius fragment

Exclusion criteria

- Age < 18 years
- Previous injury with persistent functional impairment of the fracture site
- Non-operative treatment
- Complicated (open) fractures requiring a free flap
- Pathological fractures
- No understanding of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-01-2023
Enrollment:	492
Type:	Actual

Medical products/devices used

Generic name:	Virtual 3D planning
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-10-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-09-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL81122.042.22