


STUDY PROTOCOL

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Conservative or operative therapy in patients with a fragility fracture of the pelvis: study protocol for a prospective, randomized controlled trial

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Abstract

Background The incidence of fragility fractures of the pelvis is rising. Whereas the treatment for FFP type I, III, and IV is clear, the optimal treatment for FFP type II remains a topic of discussion. Traditionally these fractures have been treated conservatively. However, there is a shift toward early surgical stabilization with percutaneous screw fixation to reduce pain and promote mobility in an already frail patient population. High-quality evidence, however, is lacking. Therefore, a randomized clinical trial was designed to compare conservative management to early percutaneous screw fixation in patients with type II fragility fractures.

Methods This is a monocenter randomized controlled trial. All patients with a FFP type II are screened for inclusion. After obtaining informed consent, patients are randomized between conservative management and surgical stabilization. Conservative management consists of early mobilization under guidance of physiotherapy and analgesics. Patients randomized for surgical treatment are operated on within 72 h using percutaneous screw fixation. The primary endpoint is mobility measured by the DEMMI score. Secondary endpoints are other dimensions of mobility, pain levels, quality of life, mortality, and morbidity. The total follow-up is 1 year. The required sample size is 68.

Discussion The present study aims to give certainty on the potential benefit of surgical treatment. Current literature on this topic remains unclear. According to the volume of FFP at the study hospital, we assume that the number of patients needed for this study is gathered within 2 years.

Trial registration ClinicalTrials.gov NCT04744350. Registered on February 8, 2021.

Keywords Fragility fractures, Pelvis, Sacroiliac, Mobility, Percutaneous screw fixation

Background

The incidence of osteoporotic fractures is rising due to an aging population. These fractures are typically the results of low-energy trauma, such as a fall from standing height. One of the most common osteoporotic fractures are pelvic fractures in the elderly. These low-energy fractures differ substantially from their high-energy counterpart. Whereas high-energy pelvic fractures are often mechanically unstable requiring immediate surgical attention,

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in low-energy pelvic fracture, typically, the weak osteoporotic bone is fractured and the ligaments remain intact resulting in an undisplaced or minimally displaced pelvic ring. However, the apparent relative instability of the pelvic ring in combination with the poor bone quality in this patient collective may subsequently lead to fracture progression or insufficiency fractures of the remaining pelvic ring [1]. These fractures are therefore often referred to as fragility fractures of the pelvis (FFP) [2].

According to the classification system, a treatment algorithm was developed by Rommens and Hofmann. FFP type I and II are primarily managed conservatively and FFP type III and IV primarily surgically. In recent years, there has been a shift toward more interventional management of type II FFP fractures. These types of fractures are frequently either misclassified or have a tendency to progress to a higher fracture grade [3]. Moreover, pain limits the mobility which has a detrimental effect in an already frail patient population [4]. Consequently, early surgical stabilization using percutaneous screw fixation is increasingly being performed to limit pain induced immobilization [5, 6].

Percutaneous screw fixation was first described in 1996 by Routt et al. [7]. Since then its safety and feasibility have improved significantly mainly due to 3D technology and intra-operative guidance for screw positioning [8, 9]. The minimally invasive character of percutaneous screw fixation makes it particularly suitable in a frail patient population such as FFP type II patients.

A study on early surgical stabilization of FFP type II fractures with percutaneous screws has shown promising results [10]. However, good quality data on this topic is lacking. Randomized clinical trials comparing percutaneous screw fixation to conservative management are necessary to determine whether screw fixation truly increases mobility and, in extension to that, reduces mortality/morbidity in this frail patient population.

Methods

Study objective

This study aims to compare early percutaneous screw fixation to conservative management for patients with FFP type II fractures. We hypothesize that early surgical treatment leads to faster mobilization in this frail patient population.

Study design

The present study encompasses a single center prospective superiority randomized clinical trial with a parallel group design. Patients are recruited at the emergency department (Figs. 1 and 2). If all inclusion criteria are met, patients are informed about the study by one of the pelvic surgeons. After informed consent is obtained, patients will directly be randomized using a sealed envelope, block randomization (computer-generated random numbers, block size 10, allocation ratio 1:1) system. This allocation is performed by an independent researcher who is not involved in this study.

Study Periods	Screening	Baseline	Treatment*	Treatment, Intervention Period		Follow-up	
				Surgical Ward, direct postoperative	Surgical Ward, pre discharge	6 weeks out-patient clinic	1 year
Location / timepoint	Emergency department / outpatient clinic	Hospital	Surgical room	Surgical Ward, direct postoperative	Surgical Ward, pre discharge	6 weeks out-patient clinic	1 year
Eligibility screening	x						
Informed Consent	x						
Randomisation	x						
Demographics		X					
Medical history		X				x	x
Current medication		X		x	x	x	x
Physical examination		X			x	x	x
Primary endpoint				x	x	x	x
Secondary endpoints		X		x	x	x	x
Intraoperative specifics			x				
Radiology		CT	CT			X-ray	X-ray
Adverse Events		x	x	x	x	x	x

Fig. 1 SPIRIT figure. Schedule of enrollment, intervention, and assessment. *Only applicable for patients randomized for operative treatment

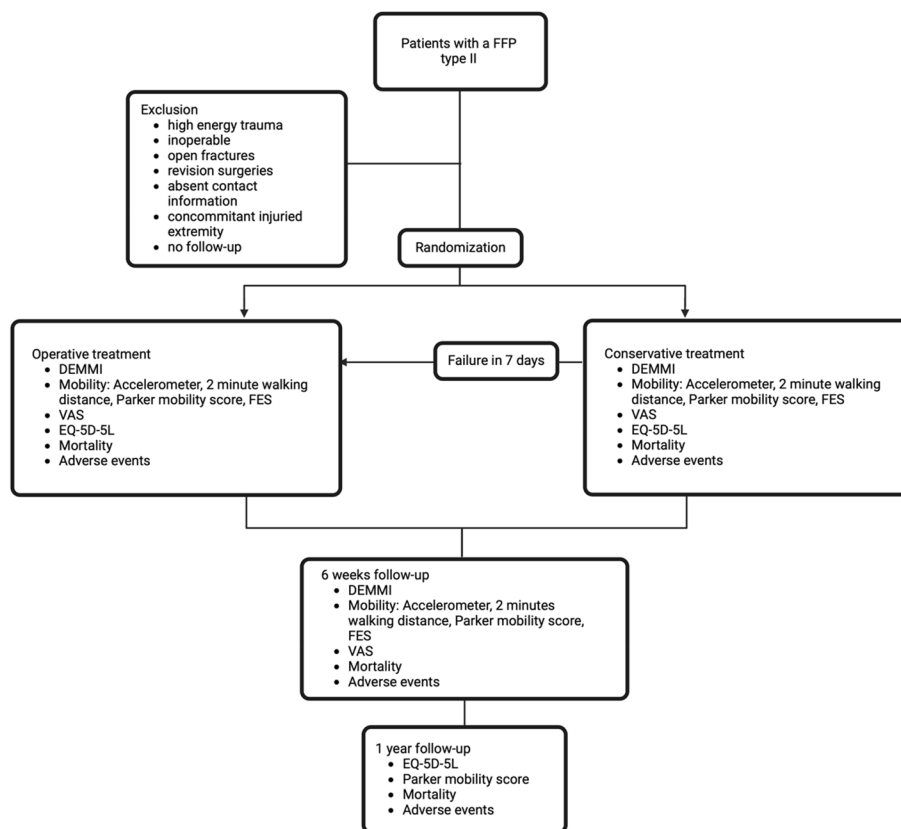


Fig. 2 Flow diagram

While blinding of the pelvic surgeon as well as the patient is not possible, the assessors measuring the primary outcome are blinded for treatment received.

Study population

Inclusion criteria

- Written informed consent
- FFP type II
- Ability to walk 4 m before trauma

Exclusion criteria

- High-energy trauma
- FFP type I, III, or IV
- Inoperable patients
- Open fractures
- Revision surgeries
- Concomitant fractures of the upper or lower extremity
- Absent contact information or living abroad and cannot participate in follow-up visits

Study endpoints

Primary endpoint

The primary endpoint is improvement in mobility using the de Morton mobility index (DEMMI score). The DEMMI is measured by one of the four trained physiotherapists at day 4 ± 1 day after initiation of conservative therapy or surgery. The DEMMI will also be scored at 6-week follow-up in the outpatient clinic [11].

Secondary endpoints

In our experience, elderly people have difficulties reporting on their level of mobility. Therefore, we chose to use an accelerometer to quantify this. Previous literature has shown that fear of falling and pain levels have a high impact on mobility in elderly. This is best measured with a fear-of-falling questionnaire and pain levels with the visual analogue score (VAS) for pain [12]. Just as important as regaining pretraumatic mobility is regaining independence and living at home. This is measured with the Parker mobility index and quality of life [13]. The specific measurement time points and measurement characteristics are explained below.

- Other mobility dimensions:

- Accelerometer (ActivPAL) during the entire hospital stay. The accelerometer is applied following manufacturer instruction at the upper leg of the patient in an upright position. At 6-week follow-up, the accelerometer is applied again to measure the mobility during a period of 1 week in the out of hospital setting. After 1 week, the patient returns the accelerometer. The output generated by the accelerometer is continuous data. Per day it is measured how many steps the patient has taken (amount of steps per day), how many times the patient stood up (amount of times per day), and how long the patient spent walking, standing, sitting, or lying (minutes per day).
 - Physiotherapist assessment using 2-min walking distance during hospitalization at day 4 ± 1 day and at the 6-week follow-up.
 - Parker mobility score at baseline, 6-week follow-up, and 1-year follow-up.
 - Fear-of-falling questionnaire also filled out at 6-week follow-up and 1-year follow-up.
- Pain levels measured by VAS everyday during hospitalization, at 6-week follow-up, and 1-year follow-up.
 - General quality of life measured by the EQ-5D-5L at baseline (pre-injury), 6-week follow-up, and 1-year follow-up.
 - Mortality.
 - All (severe) adverse events classified by the Clavien-Dindo classification [14]. Specific adverse events of interest include:
 - Screw misplacement defined as screw perforation into the neuroforamina or ventral cortex of S1.
 - Cement leakage into the neuroforamina.
 - Screw migration during follow-up.
 - Bleeding requiring intervention.
 - Fracture-related infection [15].

Patients who miss their follow-up consultation are contacted for a new appointment. All follow-up consultations will be face-to-face with the exception of the 1-year consultation for which patients can opt for a telephonic interview. Apart from the option of a telephonic interview, there are no other plans to fulfill a missed annual check-up.

Sample size calculation

The sample size was based on the expected difference between treatment groups in improvement on DEMMI score between baseline and 6-week follow-up. Previous studies using the DEMMI in patients treated for hip fractures have found an average score of 61 after operation

with an average improvement of 22 point (standard deviation 14) [16]. It is expected that conservative management will lead to less improvement. To show the minimal clinical important difference of the DEMMI score (10 points) with $\beta = 80\%$ and $\alpha = 5\%$, a total of 31 patients per group are required to attain statistical significance [11]. Accounting for 10% loss-to-follow-up, a total of 68 patients are included.

Treatment strategies

Both groups receive a standard set of co-interventions such as adequate analgesics and intensive physiotherapy.

Surgical arm

Patients randomized for surgical treatment will undergo a percutaneous iliosacral screw osteosynthesis within 72 h. In general, a percutaneous iliosacral screw osteosynthesis in the S1 body is performed on every side with an evident fracture on the CT. If patients undergoing screw fixation also have pain on the contralateral side, screw fixation will also be performed irrespective whether a fracture is seen on CT. The reason for this lies in the fact that fracture progression is frequently seen in this particular subgroup of patients [1]. Depending on the fracture pattern, additional screws such as S2 screws or transiliosacral fixation may be placed.

The surgery is performed with the use of a 3D hybrid CT-scan. The screws are planned and referenced based on a calibration CT-scan. A dorsolateral skin incision is made. A k-wire is introduced and its position is verified with the predefined inlet and outlet views. After correct positioning, a 7.5-mm fully threaded screw with integrated washer is placed over the k-wire. These screws are cannulated and fenestrated at the tip, which allows for augmentation with polymethylmethacrylate (PMMA) cement. After removal of the k-wire, augmentation is performed. If additional sacroiliac screws are required, these are inserted before augmentation. If an anterior pelvic ring fracture is present, this will be addressed as well in a percutaneous manner, assuming there are no anatomical conditions that prevent this. After surgery, patients will receive the same aftercare as patients randomized for conservative management, as described in the following section.

Conservative arm

Patients randomized for conservative treatment are treated according to the current daily practice. Patients are allowed to weight bear as tolerated and will be actively mobilized on a daily basis under guidance of a physiotherapist following a standardized protocol with mobilization exercises (supplement 1). Analgesics will be

given according to local guidelines. Therefore, all patients receive a uniform treatment plan.

The effect of conservative therapy will be evaluated 7 days after initiation. If the patient is not able to transfer in bed or walk 4 steps with or without a walking aid, surgical stabilization will be offered.

In both arms, the number of physiotherapy is monitored based on daily notes in the electronic patient file.

Statistical analysis

All statistical analyses will be performed using SPSS version 25. A p value < 0.05 is regarded as being statistically significant. Baseline characteristics and the results of both groups will be compared using Pearson's chi-squared or Fisher's exact test for categorical variables and Student's t or Mann–Whitney test. The primary outcome will be analyzed using mixed linear models with random effects. The covariates of the random part of the model will be determined using restricted maximum likelihood estimation (REML) and selected on the basis of Akaike information criterion (AIC). For the fixed part, models will be constructed containing either the treatment effect adjusted for time with or without an interaction term of these components. The models will be compared using AIC. Missing data will be imputed using multiple imputation. Primarily an intention-to-treat analysis will be performed. In case more than 20% of patients randomized for conservative treatment undergo surgical stabilization (based on the aforementioned criteria), a per-protocol analysis will also be performed.

Data management

Data collection is performed by the study team and involved physicians. All physicians are trained by the study team to ensure the quality of data collection. Updates are given regularly. Supporting personal, e.g., nurses or secretaries, are informed and trained as well. Protocols are available for involved physicians and supporting personal. Source documents directly related to the study such as informed consent forms and the filled-out questionnaires are stored at the office of the primary investigator or study nurse. Other source documents such as medical treatment and medical history are digitally stored in the current health application used by the entire hospital. All study data will be archived for a minimum of 15 years after study termination. Data never leaves the hospital and is treated as normal patient-related data; therefore, confidentiality is implied. For data management, SecuTrial is used. This is an electronic data capture system. Data entry is performed by the first author. The database is only accessible with a personal user identification and password. Before data entry, the

data is checked by RAH and MR on completeness and correctness. On request, patients can have access to the data generated by the accelerometer. After completion of the trial, the results will be made publicly regardless of the magnitude or direction of the outcome. There are no publication restrictions.

Monitoring

An independent clinical trial unit (CTU) will conduct the study-specific monitoring. The monitor will periodically verify the conduct of the study and data collection to ensure that all activities are carried out according to the protocol and that data quality and documentation in the case report form (CRF) is accurate and complete. All source data and project-related files and documents are accessible to the monitor and questions are discussed during the monitoring visits. First on-site monitoring is planned after inclusion of 2–3 patients. If there are no major or critical findings detected, on-site monitoring will be planned once a year. In case of severe adverse events, the CTU and ethical committee will be informed.

If an important protocol modification is necessary, the local ethic committee, the CTU, and the trial participants will be informed by the study coordinator either via email or by telephone.

Discussion

Current literature on this topic remains unclear. Retrospective studies have shown a benefit in mortality for surgical treatment [17, 18]. However, this could have been biased by a high percentage of patients that were managed conservatively. The present study aims to solve this uncertainty.

FFP are diagnosed about 70 times per year at the study hospital. Approximately 75% are type II FFP. It is, therefore, expected that the number of patients needed for this study ($n = 68$) may be gathered within 2 years.

It should be acknowledged that a certain amount of patients, randomized for conservative treatment, may ultimately need surgical treatment (switch-over). This might support the hypothesis that early fixation could be beneficial depending of course on what the intention-to-treat and per-protocol analysis shows in this patient population.

Abbreviations

FFP	Fragility fractures of the pelvis
LUKS	Luzerner Kantonsspital
DEMMI	De Morton mobility index
EQ-5D-5L	European Quality of Life Five Dimension
VAS	Visual analogue scale
CTU	Clinical trial unit
REML	Restricted maximum likelihood estimation
AIC	Akaike information criterion
CRF	Case report form

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-024-08350-z>.

Additional file 1. Patient information.

Additional file 2. Table 1 SPIRIT 2013 checklist.

Trial status

Protocol version: 1.4

Start recruitment: 01.11.2022.

Due to organizational issues, we were unable to submit the protocol before recruitment start. However, ethical approval and trial registration were obtained before recruitment start.

Authors' contributions

The authors RAH, BCL, MR, and BvdW designed the study. RAH wrote the manuscript. MR was responsible for the physiotherapy part and organization of the accelerometer. All authors have critically read, provided substantial revisions, and approved the final manuscript.

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This study is not funded.

Availability of data and materials

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This protocol has been approved by the Swiss ethical committee, chapter "EKNZ Zentralschweiz." The trial is registered at ClinicalTrials.gov and known under project number NCT04744350. This study will be conducted according to the principles of Good Clinical Practice. Written informed consent is obtained from of patients prior to inclusion.

Competing interests

The authors declare that they have no competing interests.

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