

Costs and effects of orthogeriatric co-management in older patients with an osteoporotic fracture in Belgium

Submission date 27/04/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/07/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 17/04/2024	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Osteoporotic fractures are a result of osteoporosis, when the bones become more fragile due to bone deterioration or low bone mass. Osteoporotic fractures are highly prevalent in our ageing population. In Belgium, the amount of osteoporotic fractures is estimated at 100,000 per year with major osteoporotic fractures (hip, pelvis, femur, forearm, shoulder, and vertebrae) accounting for almost half of these fractures. Osteoporotic fractures often lead to poor outcomes in these older persons due to complications, functional decline, institutionalization, poor quality of life, and death. Osteoporotic fractures also have a huge socio-economic impact related to hospitalizations, rehabilitation, and long-term care, and also professional and informal caregiver home care. As such, the costs during the first year after a hip fracture are very high with inpatient care as the main driver. The gold standard in Belgium (Royal Decree from 2007, updated in 2014) for the care for older patients admitted to non-geriatric wards is a mobile geriatric consultation team that acts upon request of the non-geriatric ward. However, evidence has shown that this care model has limited effects on patients outcomes. A more holistic approach by a multidisciplinary team based on the principles of comprehensive geriatric assessment has been shown to improve older patient outcomes and costs. Therefore, a shift is seen towards geriatric co-management. This type of care model has shown beneficial effects in multiple randomized controlled trials compared to the consultation model: shorter length of stay, lower death rates and readmissions. As such, the co-management model is the standard of care in several European countries (UK, Norway). Real-live data from European countries suggests indeed improved patient outcomes, however coming with a very high financial cost, questioning the cost-effectiveness of geriatric co-management. Hence, costs and reimbursement policies differ from country to country. Therefore it is highly relevant to compare the (cost)effectiveness of both models in the specific Belgian setting in order to guide policymakers in supporting management decisions.

Who can participate?

Patients aged 75 years and older who were hospitalized with a major osteoporotic fracture in Belgian hospitals in 2019.

What does the study involve?

The researchers will compare the consultation model (standard of care) with the orthogeriatric co-management model.

Standard of care is defined as surgical care with geriatric expertise that is available upon active request by the trauma team and includes the comprehensive evaluation of the patient by a geriatric nurse.

Orthogeriatric co-management is defined as systematic involvement by a geriatrician and geriatric team in addition to the involvement of the surgical team. As the geriatric care provided is systematic, it is considered proactive. This is in contrast to a reactive model where geriatric care relies on a question for advice posed by the orthopaedic team.

What are the possible benefits and risks of participating?

There are no immediate direct benefits or risks to those taking part.

Where is the study run from?

University Hospital at Leuven (Belgium)

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

August 2022 to July 2024

Who is funding the study?

KU Leuven (Belgium)

Who is the main contact?

Prof. Dr Marian Dejaeger

marian.dejaeger@uzleuven.be

Contact information

Type(s)

Principal Investigator

Contact name

Prof Marian Dejaeger

ORCID ID

<http://orcid.org/0000-0002-7289-1397>

Contact details

Herestraat 49

Leuven

Belgium

3000

+32 (0)16 340932

marian.dejaeger@uzleuven.be

Type(s)

Scientific

Contact name

Miss Sigrid Janssens

ORCID ID

<http://orcid.org/0000-0003-2652-2336>

Contact details

Herestraat 49

Leuven

Belgium

3000

+32 (0)16 34 42 45

sigrid.janssens@uzleuven.be

Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information**Scientific Title**

Orthogeriatric co-management vs standard of care: health technology assessment evaluation in older patients with an osteoporotic fracture in Belgium

Study objectives

It is hypothesized that on a nationwide level orthogeriatric co-management will be more effective compared to the current geriatric consultation model to reduce mortality and readmissions and that it will be more cost-effective from a payer perspective as well.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval is not required. This is a retrospective study, which means that the Belgian law of 07/05/2004 on experiments on human persons is not applicable.

Study design

Retrospective population-based data-registry study

Primary study design

Observational

Secondary study design

Retrospective population-based data-registry study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Improving care for older patients with a fracture

Interventions

Standard of care:

Standard of care is defined as surgical care with geriatric expertise available upon active request by the trauma team and includes the comprehensive evaluation of the patient by a geriatric nurse (consultation model).

Orthogeriatric co-management:

Orthogeriatric co-management is defined as systematic involvement by a geriatrician and geriatric team in addition to the involvement of the surgical team. As the geriatric care provided is systematic, it is considered proactive. This is in contrast to a reactive model where geriatric care relies on a question for advice posed by the orthopaedic team.

Intervention Type

Behavioural

Primary outcome measure

1. Effectiveness evaluation:

1.1. Mortality evaluation at 1 year after admission

2. Cost-effectiveness evaluation:

2.1. The survival time within 1 year will be estimated time in days from admission to the hospital

2.2. The costs included will be in-hospital costs (e.g., physiotherapy, imaging, hospitalization) and long-term costs during the first year after discharge (e.g., professional care at home, nursing home)

Data will be collected by the Intermutualistic Agency

Secondary outcome measures

1. Effectiveness evaluation:

1.1. Mortality evaluation at 30 days and 90 days after admission

1.2. The Inpatient length of stay will be the estimated time in days between discharge and admission

1.3. Return to pre-fracture living situation, specified as living at home or in a nursing home and compared to the living situation before admission

1.4. Hospital readmissions and emergency department visits evaluation within 30 and 90 days after discharge

Data will be collected by the Intermutualistic Agency

Overall study start date

01/08/2022

Completion date

01/07/2024

Eligibility

Key inclusion criteria

1. Patients aged 75 years and over on the day of admission
2. Admission to a listed Belgian hospital (information on the used care model and consent has been provided by representative medical doctors from listed hospitals)
3. Admission via the emergency department in case of arthroplasty of hip and/or shoulder
4. Reason for admission: major osteoporotic fracture (hip, pelvis, femur, shoulder, forearm, and vertebrae; the selection will be based on RIZIV nomenclature)
5. First admission to Belgian hospital in period: 01/01/2019 - 31/12/2019 (to avoid interference with the COVID-19 pandemic and to ensure full data availability)

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

40,000

Key exclusion criteria

1. Patients below 75 years of age on admission
2. Patients admitted to a Belgian hospital that is not on the list of included hospitals
3. Patients undergoing an arthroplasty of the hip and/or shoulder who were NOT admitted via the emergency department to ensure that a fracture was the reason for admission and treatment

Date of first enrolment

01/06/2023

Date of final enrolment

30/11/2023

Locations

Countries of recruitment

Belgium

Study participating centre
UZ Leuven
Herestraat 49
Leuven
Belgium
3000

Sponsor information

Organisation

KU Leuven

Sponsor details

Herestraat 49
Leuven
Belgium
3000
+32 (0)16 342647
johan.flamaing@uzleuven.be

Sponsor type

University/education

Website

<http://www.kuleuven.be/english>

ROR

<https://ror.org/05f950310>

Funder(s)

Funder type

University/education

Funder Name

KU Leuven

Alternative Name(s)

Katholieke Universiteit Leuven

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Belgium

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal in open-access

Intention to publish date

01/04/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the privacy of the participants. Data will be collected by the Intermutualistic Agency (IMA). IMA collects insurance claims data covering the total Belgian population. IMA will host the data and make it available in a secured way to the researchers via a Trusted Third Party. After finishing the study and publication of the manuscripts, the data will be destroyed and will therefore not be available anymore.

IPD sharing plan summary

Not expected to be made available