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Orthogeriatric co-management for older patients with a major osteoporotic fracture: a hybrid effectiveness-implementation study

Submission date
28/09/2021

Registration date
11/10/2021

Last Edited
17/10/2023

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

✓ Prospectively registered
✓ Protocol added
? SAP not yet added
? Results not yet added and study completed for less than 1 year
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Osteoporosis is the most common musculoskeletal disease and can lead to fractures of the hip, spine, proximal humerus (upper arm bone), pelvis and wrist. These fragility fractures are associated with pain, disability, need for institutionalization and even death. The complex needs of the older fracture patient require a multidisciplinary approach. At the moment there is little cooperation between geriatricians and surgeons in Belgium due to the current care organization with a silo mentality. The focus has shifted to different forms of collaboration, such as co-management with proactive care and shared responsibility between geriatric and non-geriatric team members. Due to the successful results of such co-management models, researchers have set up a care strategic project for geriatric-surgical co-management within the University Hospitals Leuven, named G-COMAN.
This study will evaluate the effectiveness of the geriatric-traumatology part of the G-COMAN program and will examine which factors contribute to a (non)successful implementation of the program.

Who can participate?
Hospitalised patients aged 75 years or older with a fragility fracture on the Traumatology ward of the University Hospitals Leuven

What does the study involve?
The usual care group will be treated by the regular trauma team and receive geriatric advice solely upon active request by the traumatology team. The patients in the geriatric co-management intervention group will receive a comprehensive assessment by a traumatology nurse trained in geriatric care. Based on identified potential problems a personalized care plan based on predefined geriatric protocols will be launched. The main outcome that will be evaluated in both groups is in-hospital complications. Length of hospital stay, unplanned readmissions within 30 days, death, functional status, nutritional status, quality of life, falls and new fracture rate, return to pre-injury residential status and secondary fracture prevention

started will also be observed and evaluated. Process outcomes will be assessed to evaluate the implementation of the programme.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. However, the results of this study are expected to generate important evidence on the effectiveness of a nurse-led geriatric-traumatology co-management model. The process evaluation will offer a better understanding about how the co-management model is implemented, will help to optimise it more and provide insights into how this model can be further up-scaled and firmly embedded into routine clinical practice.

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?
February 2021 to October 2024

Who is funding the study?
KU Leuven (Belgium)

Who is the main contact?
Prof. Dr Marian Dejaeger
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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

Protocol/serial number
s65569 / B3222021000527

Study information

Scientific Title
Geriatrics and traumatology CO-MANaging fragility FRACTURES: effectiveness and success of implementation in a single centre setting

Acronym
GCOMAN FRACTURES

Study hypothesis
Current study hypothesis as of 27/06/2022:
Orthogeriatric co-management is superior over standard care in preventing in-hospital complications in older fracture patients.

Previous study hypothesis:
Geriatric-traumatologic co-management is superior over standard care in preventing in-hospital complications in older fracture patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/08/2021, Ethics Committee Research UZ/KU Leuven (Herestraat 49, B 3000, Leuven, Belgium; +32 (0)16 34 86 00; ec@uzleuven.be), ref: S65569

Study design
Observational pre-post effectiveness-implementation study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
Improving care for older fragility fracture patients

Interventions
Usual care (pre-cohort):
The control group receives usual care on the trauma ward. This means that the patient is cared for by a surgical resident. The interprofessional team furthermore consists of ward nurses, a physiotherapist, an occupational therapist and a social worker. No tailored geriatric protocols are available to the trauma team, except for those that are available hospital-wide for all patients (e.g. fall prevention, delirium). Geriatric expertise is available upon active request by the trauma team and includes the comprehensive evaluation of the patient by a geriatric nurse (consultation model).

Geriatric co-management intervention, quality-improvement project G-COMAN (post-cohort):
As part of the project every weekday a geriatric specialist nurse will provide training and education of the geriatric reference nurse on the trauma ward. This geriatric reference nurse on the trauma ward will coach the whole trauma care team to perform proactive geriatric care in conjunction with automated geriatric protocols. Furthermore, a tailored care plan based on a comprehensive geriatric assessment (CGA) will be launched. The implementation of automated care plans and predefined geriatric protocols will be coordinated by a G-COMAN project coordinator, as well as the organisation of focus groups and interventions to ensure smooth and supported collaboration.

Intervention Type
Behavioural

Primary outcome measure
In-hospital complications (delirium, congestive heart failure, pneumonia, deep venous thrombosis, pulmonary embolism, myocardial infarction or urinary tract infection), measured by 4AT by:
1. Suspicion of delirium
2. Diagnosis of congestive heart failure based on the Modified Framingham Criteria
3. Diagnosis of pneumonia through imaging and laboratory testing according to local standard of care
4. Diagnosis of deep venous thrombosis confirmed on imaging (ultrasound) as per local standard

of care
5. Diagnosis of pulmonary embolism confirmed on imaging through CT scans or radionuclide examination
6. Diagnosis of myocardial infarction defined as evidence of myocardial necrosis consistent with myocardial ischemia and urinary tract infection based on laboratory testing and relevant symptomatology
All measured during hospitalization

Secondary outcome measures

1. Patient outcomes:
1.1. Length of hospital stay defined as the total of days between admission and discharge at discharge
1.2. Quality of life measured using the EQ-5D at admission, discharge, 1, 3, 6 and 12 months post-discharge
1.3. Functional status and mobility measured using the Parker Mobility Score, modified Barthel Index/Katz index, Lawton and Brody Scale and at admission, discharge, 1, 3 and 6 months post-discharge
1.4. Hospital readmissions measured by a questionnaire and hospital records as any admission to hospital after discharge in the first 30 days post-discharge
1.5. Falls ("an unexpected event in which the patients comes to rest on the ground, floor or lower level") and new fractures measured by a questionnaire at admission, in-hospital, at discharge, at 1, 3, 6 and 12 months post-discharge
1.6. Residential status defined in five categories: living alone at home, living with spouse /partner, living with children, assisted living, living in a facility with 24 h care such as a nursing home measured by a questionnaire at admission, discharge, 1, 3 and 12 months post-discharge
1.7. Mortality evaluation in-hospital at 1 and 12 months post-discharge
1.8. Secondary fracture prevention including documentation of fall risk assessment, medication review measured by a questionnaire and hospital records at admission, discharge, 1, 3, 6 and 12 months post-discharge
1.9. Nutritional status measured using the Mini Nutritional Assessment (MNA) at admission, 1, 3 and 6 months post-discharge

2. Process outcomes:
2.1. The reach of the program measured as % of patients aged 75 or older that are enrolled in the G-COMAN program, measured during hospitalization
2.2. The fidelity of the program measured as % of patients included in G-COMAN who had a screening or assessment focusing on delirium, nutritional status, pressure ulcer risk using a validated tool within 48 h of admission to traumatology ward, measured during hospitalization.
2.3. Time to start physiotherapy measured as registration in the electronic patient file and/or daily evaluation on the ward, measured during hospitalization
2.4. Time to start dietary advice measured as registration in the electronic patient file and/or daily evaluation on the ward, measured during hospitalization
2.5. Use and duration of physical restraints measured as registration in the electronic patient file and/or daily evaluation on the ward, measured during hospitalization
2.6. Use and duration of indwelling catheters measured as registration in the electronic patient file and/or daily evaluation on the ward, measured during hospitalization
2.7. Medication reconciliation concerning secondary fracture prevention measured by questionnaire at admission, discharge and 12 months discharge
2.8. Referral to geriatric day clinic measured as an appointment for geriatric day clinic in UHL in

the year following the first admission
2.9. Referral to fracture liaison services measured as an appointment for the metabolic bone centre in UHL or zoledronate infusion in the year following the first admission

Overall study start date
01/02/2021

Overall study end date
01/08/2024

Eligibility

Participant inclusion criteria
1. Aged 75 years and over at hospital admission
2. Admission on traumatology ward (E456) UZ Leuven due to new osteoporotic fracture: proximal femoral fracture, proximal humeral fracture, fracture of the pelvis/acetabulum, fracture of the thoracic/lumbar vertebrae (multiple fractures are allowed), fracture of the wrist

Participant type(s)
Patient

Age group
Senior

Lower age limit
75 Years

Sex
Both

Target number of participants
216

Total final enrolment
216

Participant exclusion criteria
1. Does not speak and/or understand Dutch
2. Palliative care setting (<3 months prognosis)
3. Multiple fractures (exception multiple vertebral fractures at the same moment)
4. Reoperation for surgical complication
5. Periprosthetic fracture
6. Concomitant joint infection

Recruitment start date
25/10/2021

Recruitment end date
10/07/2023

Locations

Countries of recruitment
Belgium

Study participating centre
UZ Leuven
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Sponsor information

Organisation
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Sponsor type
University/education

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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
01/10/2025

Individual participant data (IPD) sharing plan
Anonymized study data will be available on request. Data will be collected using REDCap®, an electronic case report from (eCRF) that entails a possibility to export data into an Excel file. Colleague researchers can request all necessary data, e.g for meta-analysis, which the researchers will send in an anonymized Excel file. Data can be requested by contacting Prof. Dr Marian Dejaeger (by mail) after publication of the study in a peer-reviewed journal. The patients will have signed an informed consent form (in Dutch) in which they agree to use the collected data for scientific research and for publication, provided that the Belgian and European law concerning privacy protection is respected. This means that only anonymized data will be shared.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	22/04/2022	27/06/2022	No	No
Protocol article		05/04/2023	06/04/2023	Yes	No
Other publications		30/08/2023	15/09/2023	Yes	No