

Aging of the endocrine system and clinical outcome of frail elderly patients with fractures

Submission date 13/02/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/10/2022	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hip fractures are cracks or breaks in the top of the thigh bone close to the hip joint, usually caused by a fall or an injury. They are a severe complication in frail elderly patients. The aim of this study is to assess endocrine (hormone) system changes in elderly frail patients and their relationship with frailty.

Who can participate?

Patients aged over 65 who have been hospitalised following hip fracture, and outpatients without hip fracture

What does the study involve?

Participants' weight and height are measured and their medical history is recorded, including drugs taken chronically (long-term). Participants undergo an extensive clinical evaluation to assess their degree of frailty, and undergo a physical examination and blood sampling for laboratory tests of hormone levels.

What are the possible benefits and risks of participating?

Participants benefit from an extensive clinical evaluation and follow-up. No risks are expected.

Where is the study run from?

University Hospital "Tor Vergata" (Italy)

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

January 2014 to December 2017

Who is funding the study?

University of Rome "Tor Vergata" (Italy)

Who is the main contact?

Dr Aldo Bertoli

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

Ethical Committe "Tor Vergata" Protocol n. 72/14, 29/04/2014

Study information

Scientific Title

Aging of the endocrine system and clinical outcome of frail elderly patients with fractures: an observational study

Study objectives

To evaluate the role of endocrine system aging in the clinical outcome of elderly patients with low energy fracture.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study design

Cross-sectional case-control observational study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Aging and frailty

Interventions

The study was aimed to evaluate the prevalence of endocrine system modifications in elderly frail subjects and its relationship with frailty. Subjects with hip fracture and outpatients without fracture were evaluated. Each patient's sex and age were recorded, anthropometric parameters were measured (weight and height), and the body mass index (BMI) was calculated. The medical history of each patient was recorded, including drugs taken chronically. Participating patients received a multidimensional geriatric evaluation comprising the following scales: Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL); Mini-Mental State Examination (MMSE); Geriatric Depression Scale (GDS); and Mini Nutritional Assessment (MNA). Frailty was measured using SHARE-FI and major osteoporotic and hip risk measured by FRAX Score tool. Comorbidities were assessed using the Cumulative Illness Rating Scale for Geriatrics (CIRS-G), from which we obtained the CIRS severity (CIRS-S), CIRS comorbidity index (CIRS-CI), and Charlson comorbidity index (CCI).

All study participants underwent physical examination and blood sampling for laboratory assays (blood count, creatinine, glucose, albumin, electrolytes, serum cortisol, TSH, free T3 [FT3], free T4 [FT4], IGF-1, GH, DHEAS, PTH, Vitamin D, OPG, OC, high-sensitivity C-reactive protein [hs-CRP], interleukin-6 [IL-6] and tumor necrosis factor- α [TNF- α]). Serum, plasma and DNA samples are stored at -80 °C for further eventual examinations.

Intervention Type

Mixed

Primary outcome(s)

Prevalence of endocrine system abnormalities, measured using blood sampling for laboratory assays at baseline (serum cortisol, TSH, free T3 [FT3], free T4 [FT4], IGF-1, GH, DHEAS, PTH, Vitamin D, OPG, OC, interleukin-6 [IL-6] and tumor necrosis factor- α [TNF- α])

Key secondary outcome(s)

1. Disability, measured using ADL (Activities of Daily Living) and IADL (Instrumental Activities of Daily Living) at baseline and 1 and 2 years follow-up
2. Cognitive impairment, measured using Mini-Mental State Examination (MMSE) at baseline
3. Nutritional status, measured using Mini Nutritional Assessment (MNA) at baseline and 1 and 2 years follow-up
4. Comorbidities, assessed using Cumulative Illness Rating Scale for Geriatrics (CIRS-G) and

Charlson comorbidity index (CCI) at baseline

5. Frailty, measured by SHARE-FI at baseline

6. Major osteoporotic and hip risk, measured by FRAX Score tool at baseline

7. Mortality and recurrence of fracture, measured at 1 and 2 years follow-up

Completion date

12/12/2017

Eligibility

Key inclusion criteria

1. Patients hospitalized in the Orthopedic Department after a hip fracture

2. Control subjects enrolled among outpatients evaluated at the Department of Medicine (Clinical Program on Atherosclerosis)

3. Age over 65 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

112

Key exclusion criteria

Presence of a malignancy or a history of previous cancer

Date of first enrolment

01/05/2014

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

Italy

Study participating centre

Polyclinic of Rome, "Tor Vergata"

Viale Oxford, 81

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Sponsor information

Organisation

University of Rome "Tor Vergata"

ROR

<https://ror.org/02p77k626>

Funder(s)

Funder type

University/education

Funder Name

Università degli Studi di Roma Tor Vergata

Alternative Name(s)

University of Rome Tor Vergata

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Italy

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during an/or analysed during the current study will be stored in non-publicly available repository.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type
[Results article](#)

Details

Date created
10/02/2017

Date added
05/10/2022

Peer reviewed?
Yes

Patient-facing?
No