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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
13/02/2017		☐ Protocol		
Registration date 25/04/2017	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
05/10/2022	Other			

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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Comitato Etico Indipendente, Fondazione PTV Policlinico Tor Vergata (Ethical Committee of the Polyclinic Tor Vergata), 04/06/2014, ref: 72/14

Study design

Cross-sectional case-control observational study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

No participant information sheet available

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 measure

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])

Secondary outcome measures

- 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 Assesment (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

Overall study start date

01/01/2014

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

Age group

Senior

Sex

Both

Target number of participants

200

Total final enrolment

112

Key exclusion criteria

Presence of a malignancy or a history of previous cancer

Date of first enrolment

Date of final enrolment 31/12/2017

Locations

Countries of recruitment

Italy

Study participating centre
Polyclinic of Rome, "Tor Vergata"
Viale Oxford, 81
Rome
Italy
I-00133

Sponsor information

Organisation

University of Rome "Tor Vergata"

Sponsor details

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Sponsor type

University/education

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

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal. The intention is to publish first data in February 2017.

Intention to publish date

01/02/2017

Individual participant data (IPD) sharing plan

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

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/02/2017	05/10/2022	Yes	No