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

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| **Submission date**<br>13/02/2017 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>25/04/2017 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>05/10/2022 | **Condition category**<br>Other | [_] 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

**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

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"

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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 |