ISRCTN03362357 https://doi.org/10.1186/ISRCTN03362357

Parathyroid hormone in the recovery from hip fractures: a pilot study

Submission date	Recruitment status
31/12/2010	No longer recruiting
Registration date	**Overall study status**
03/03/2011	Completed
Last Edited	**Condition category**
03/02/2014	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
R&D 2185

Study information

Scientific Title
The administration of intermittent parathyroid hormone affects functional recovery from pertrochanteric fractured neck of femur: a prospective mixed method pilot study with randomisation of treatment allocation and blinded assessment

Acronym
FRACTT

Study objectives
1. It is possible to recruit 50% of the eligible participants to this trial design
2. It will be possible to manage this study design to International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) guidelines
3. The use of a daily injection pen for 6 weeks in the elderly acutely injured population is acceptable and feasible

Planned null hypothesis for full trial:
The administration of daily parathyroid hormone (PTH) will have no difference on functional recovery from pertrochanteric fracture of the femur in elderly patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West 2 Research Ethics Committee approved on the 3rd November 2010 (ref: 10/H0206/34)

Study design
Open label single centre prospective randomised comparative pilot study with a nested qualitative study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hip fractures

Interventions
Intervention: tereparatide (Forsteo®) 20 µg/day injections
Comparator: standard care

Total duration of treatment: 6 weeks
Total duration of follow up: 6 months

Subjects participating in nested qualitative study will be followed for 12 months.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)

Parathyroid hormone

Primary outcome(s)
Participant numbers including recruitment rate, drop out rate, mortality rates, measured at baseline, 6 weeks, 3 months, 6 months (+12 months for qualitative sub group)

Key secondary outcome(s))
1. Short Physical Performance Battery, measured at 6 weeks, 3 months (+6 months and 12 months for qualitative sub study)
2. 36-item Short Form Health Survey (SF36), measured at 6 weeks, 3 months, 6 months by phone (+ 12 months for qualitative sub study)
3. EQ5D, measured at 6 weeks, 3 months, 6 months by phone (+ 12 months for qualitative sub study)
4. Visual Analog Scale (VAS) pain, measured at 6 weeks, 3 months, 6 months by phone (+ 12 months for qualitative sub study)
5. Compliance rates, measured at 6 weeks

Completion date
01/05/2013

Eligibility

Key inclusion criteria
Patients admitted to Frenchay Hospital with diagnosis of a pertrochanteric femoral fracture over the age of 60 years (either sex)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
Patients with any of the following would be excluded from the trial:
1. Fracture not as a result of a low energy injury/fall for example fall from standing height
2. Patients whose fracture is managed conservatively
3. Surgical fixation with total hip replacement (THR), hemiarthoplasty or cannulated screws
4. Previous treatment with PTH or other PTH analogues.
5. Hypersensitivity to the active substance or to any of the excipients.
6. Previous IV bisphosphonate (e.g. Zoledronic acid) in the previous 12 months
7. Strontium therapy for osteoporosis within the previous12 months
8. Current medications for breast and prostate cancer (e.g. tamoxifen, anastrozole, zoladex, prostap) or other hormone therapies such as testosterone, HRT
9. Decreased capacity to understand the risks of participating in the trial,

10. Metabolic bone disease e.g. Pagets disease & hyperparathyroidism other than primary osteoporosis or glucorticoid-induced osteoporosis.
11. Pre-existing hypercalcaemia or high or low corrected calcium which requires investigation.
12. Severe renal failure (EGFR <30) or urolithiasis
13. Unexplained raised alkaline phosphatase,
14. Active cancer diagnosis or skeletal malignancies or bone metastases or prior external beam or implant radiation therapy to skeleton within the last five years.
15. Premenopausal
16. Pregnancy or lactation
17. Sustained use of oral steroids
18. Wheelchair, bed bound or transferring only prior to fracture
19. Other fractures that will affect ability to mobilise at 6 weeks
20. Physically incapable to carry out treatment protocol or appropriate social circumstances (e.g. needle phobia, other severe disabilities limiting manipulation of injection pen and without appropriate carer willing and able to assist)
21. Patient consents to study >7 days post surgery
22. Current participation in any other clinical trial of medicinal product

Date of first enrolment
08/01/2011

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Consultant Orthopaedic Trauma Surgeon
Bristol
United Kingdom
BS16 1LE

Sponsor information

Organisation
North Bristol NHS Trust (UK)

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme (ref: PB-PG-0408-16292)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/01/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes