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Can Teriparatide prevent the onset of hypocalcemia after surgical thyroid removal?

Submission date
09/04/2016

Recruitment status
No longer recruiting

Registration date
12/04/2016

Overall study status
Completed

Last Edited
08/05/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Hypoparathyroidism is a hormonal disorder in which the parathyroid glands in the neck do not produce enough parathyroid hormone. Parathyroid hormone (PTH) is responsible for regulating the amount of calcium in the blood, by acting on the bones, kidneys and intestines. If the body does not produce enough PTH then blood calcium levels fall (hypocalcaemia), leading to unusual muscle movements (such as jerking or twitching), a tingling sensation in the fingers and toes, muscle cramps, mental problems such as confusion and irritability, and even heart problems. The most common cause of hypoparathyroidism is unintentional or unavoidable damage to or removal of the parathyroid glands during surgery. Predicting the risk of a surgical patient developing hypoparathyroidism is an important part of care. It has been found that measuring intact parathyroid hormone (iPTH) during or shortly after surgery is a good method of predicting risk. Teriparatide (PTH 1-34) is drug containing a man-made form of parathyroid hormone. A recent study has shown that it able to correct blood calcium levels in patients with hypocalcemia following surgery. The aim of this study is to find out whether teriparatide is able to prevent post-surgical hypocalcemia in patients who have a high risk of developing hypocalcemia after thyroid surgery.

Who can participate?
Adults who have low iPTH levels after having part or all of the thyroid gland removed (thyroidectomy).

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive 20 micrograms of teriparatide from a trained nurse using an injection pen after surgery. This is then repeated every 12 hours until they are discharged from hospital. Participants in the second group do not receive any treatment and are observed throughout their hospital stay. Every day they are in hospital after their surgery (at least two days), participants in both groups have a sample of blood taken so that their iPTH levels can be measured. The length of time participants from each group spend in hospital is also compared.

What are the possible benefits and risks of participating?
Participants who receive treatment may benefit from improved PTH levels, avoiding

hypocalcemia. There are no notable risks of participating, although blood testing may cause pain and bruising to some participants.

Where is the study run from?
Università Campus Bio-Medico di Roma, Surgical Ward (Italy)

When is the study starting and how long is it expected to run for?
January 2016 to May 2016

Who is funding the study?
Università Campus Bio-Medico di Roma (Italy)

Who is the main contact?
Dr Andrea Palermo
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2016-000481-32

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
PTH(1-34) for the primary prevention of post-surgical hypocalcemia: the THYPOS trial

Acronym
THYPOS

Study objectives
The aim of this study is to evaluate whether teriparatide is able to prevent post-surgical hypocalcemia in subjects with high risk of hypocalcemia after thyroid surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethic Commitee Università Campus-Biomedico (Rome), 01/02/2016, ref: 16.16

Study design
Prospective phase II single-centre open label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Please see additional files

Health condition(s) or problem(s) studied
Hypocalcemia due to Post-surgical hypoparathyroidism

Interventions
Subjects with iPTH levels at 4 hours after thyroidectomy < 10 pg/ml will be enrolled. After surgery, they will be randomized (1:1) to receive treatment with teriparatide or following the standard clinical care.

Treatment group: A nurse administers 20 mcg of teriparatide using an injection pen (Forsteo® Eli Lilly Nederland B.V.) to patients immediately after randomisation. Following this, administrations will be done every 12 hours until discharge.

Control group: Participants will receive no treatment and they will be accurately observed until the discharge as suggested by national and international guidelines.

At 8.00 AM on the first and second postoperative, in fasting state, a blood sample will be drawn and calcium, phosphate, albumin, magnesium, will be measured. A clinical evaluation and ECG will be performed to exclude signs or symptoms of hypocalcemia.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Teriparatide (Forsteo®)

Primary outcome measure
1. Serum calcium is measured using hematological testing at baseline (4 hours after thyroidectomy), in the morning (from 8:00 to 8:30 AM) of postoperative day 1 and 2, and daily until the discharge (if hospitalisation lasts more than two days)
2. Signs and symptoms of hypocalcemia are determined through physical examinations at baseline (4 hours after thyroidectomy) and daily until discharge.

Secondary outcome measures
Duration of hospitalization is measured counting the days from the thyroidectomy until the discharge.

Overall study start date
04/01/2016

Completion date
10/05/2016

Eligibility

Key inclusion criteria
1. Aged 18 and over
2. Patients with a formal surgical indication for thyroidectomy.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
11 patients for each group (total number: 22). Estimating a dropout rate of 20%: total number: 26)

Key exclusion criteria
1. Aged under 18 years
2. Pregnancy
3. Renal failure (glomerular filtration rate < 30 mL/min)
4. Hypersensitivity to the active substance or excipients

5. Any prior parathyroid pathology
6. Preexisting hypercalcemia
7. Metabolic bone disease other than osteoporosis
8. Ongoing therapy for osteoporosis
9. In the last 6 months administration of calcitonin
10. Systemic corticosteroids, estrogens, raloxifene, fluoride, lithium, loop or thiazide diuretics, aromatase inhibitors or other drugs that could interfere with calcium metabolism
11. History of skeletal malignancies (primary or metastatic)
12. Active or recent urolithiasis
13. Unexplained elevation of serum alkaline phosphatase levels
14. Prior radiation therapy involving the skeleton, serum magnesium levels below the lower limits or above the upper limits of normal

Date of first enrolment
01/02/2016

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
Italy

Study participating centre
University Campus Biomedico of Rome
Surgical ward
via Alvaro del Portillo 20
Rome
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00128

Sponsor information

Organisation
Università Campus Bio-Medico di Roma

Sponsor details
Department of Endocrinology and Diabetes
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Sponsor type

University/education

ROR
https://ror.org/04gqx4x78

Funder(s)

Funder type
University/education

Funder Name
Università Campus Bio-Medico di Roma

Alternative Name(s)
Campus Bio-Medico University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Publication and dissemination plan
Planned publication in the journals JCEM, JBMR or Bone.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			13/04/2016	No	Yes
Results article	results	01/11/2016		Yes	No