Bone density in apheresis donors compared with blood donors. A pilot-study.

Published: 03-01-2012
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To investigate whether bone mineral density is lower in apheresis donors than in blood donors.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational invasive

Summary

ID

NL-OMON35222

Source
ToetsingOnline

Brief title
Bone density in apheresis donors compared with blood donors. A pilot-study.

Condition

- Bone disorders (excl congenital and fractures)

Synonym
Increased risk for osteoporosis.

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: sanquin

Intervention

Keyword: apheresis donors, blood donors, Bone mineral density, osteoporosis

Outcome measures

Primary outcome

The primary study parameter is bone mineral density, measured by dual X-ray

absorptiometry

Secondary outcome

The bone turnover markers C-telopeptide (CTX) and N-terminal propeptide of

type 1 collagen (P1NP).

Study description

Background summary

It is known that there are short term changes of serum calcium during apheresis procedures. Less is known about the consequences of this during long term follow-up, such as decrease of the bone mineral density. When this occurs, it could be advisable to supplement calcium during the apheresis procedure.

Study objective

To investigate whether bone mineral density is lower in apheresis donors than in blood donors.

Study design

case control study

Study burden and risks

Discomfort is possible during vena punction. Radiation of the DXA-scan is low, about 10-15% of that of a thorax X-ray.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women between 55 en 70 years old, who underwent apheresis donation at least a hundred times.
Control subjects: women between 55 en 70 years old who are blood donor for at least 15 years.

Exclusion criteria

- smoking
- use of certain medication during inclusion period, such as corticosteroids and bisphosphonates.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-01-2012
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL37527.029.11