MOnitoring NUtritional COnsequences of Obesity Treatment on women*s health and transgenerational effects for healthier future generations.

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The main objective is to unravel the consequences of obesity treatment on women*s longer-term health, with a primary focus on musculoskeletal health (muscle mass and bone mineral density). Transgenerational consequences of obesity treatment on…

Ethical review	Approved WMO
Status	Pending
Health condition type	Malabsorption conditions
Study type	Observational invasive

Summary

ID

NL-OMON56975

Source
ToetsingOnline

Brief title
MONUCO

Condition

- Malabsorption conditions
- Vitamin related disorders
- Musculoskeletal and connective tissue disorders NEC

Synonym
Muscle qualtiy; bone mineral density

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: 4TU HTSF,Seed Fund Alliantie Voeding in de Zorg

Intervention

Keyword: Nutrition, Obesity, Transgenerational consequences, Women's health

Outcome measures

Primary outcome

Main parameters are changes in nutrient intake and status as well as muscle mass and bone mineral density. Muscle strength, muscle fat infiltration and bone marrow adipose tissue are main outcomes of the subgroup. Main endpoints of the birth cohort are foetal growth and child development.

Secondary outcome

Secondary parameters are lifestyle factors and parameters of the endocrine and reproductive systems (i.e., menstrual complaints, thyroid function and hormonal changes).

Study description

Background summary

Although obesity treatment is effective in reducing long-term bodyweight and obesity-related comorbidities for the majority of patients with severe obesity, it also negatively impacts nutritional status (vitamins, minerals, but also proteins), which may negatively impact health, for example disproportional loss of muscle mass and bone mineral density, particularly in menopausal women. Furthermore, impaired nutritional status during subsequent pregnancy may potentially be detrimental for foetal growth and child development of the estimated 50% of women who become pregnant after obesity treatment. The transgenerational effects of obesity and obesity treatment induced maternal

nutrient deficiencies on foetal growth and child development remain unclear.

Study objective

The main objective is to unravel the consequences of obesity treatment on women*s longer-term health, with a primary focus on musculoskeletal health (muscle mass and bone mineral density). Transgenerational consequences of obesity treatment on maternal health, foetal growth and child development will be studied within the birth cohort.

Study design

Prospective observational cohort study.

Study burden and risks

Participants will be asked to complete questionnaires, to wear an accelerometer during one week, to have a BIA measurement taken, to perform a handgrip strength and chair stand test, to donate additional blood as part of regular venapuncture, and to collect urine and faeces samples.

A subgroup of participants will be asked to undergo a DEXA, MRI and legpress measurement.

Participants who become pregnant during the course of the study will be asked to collect a small amount of human milk. Foetal growth and child development will be monitored as part of usual care and collected via the mother. A subgroup of the pregnant women will be asked to have a qualitative ultrasound.

Filling out questionnaires brings no harm.
Collecting additional blood via venapuncture as part of regular care will not cause any additional bruises.
No risks have been reported for having a DEXA, MRI or quantitative ultrasound.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion criteria for the cohort:
- Female at birth
- Aged 18-55 years of age
- Living with obesity (BMI => 30kg/m^2)
- Approved for obesity treatment in one of the participating hospitals.
- Undergoing bariatric surgery (RYGB OAGB, or SG)
- Receiving obesity medication (any type) under medical supervision with BMI => 30kg/m^2)
- For those undergoing MRI, DEXA and quantitative ultrasound scan: Willing to be informed about incidental findings of pathology and approving of reporting this to their general physician.

Additional criteria for the (integrated) birth cohort:
- Being pregnant, or having pregnancy wish
- Age 18-45 years of age
- Having received prior obesity treatment (either surgical (RYGB, SG) or pharmacological, at least 4 months)

Exclusion criteria

Exclusion criteria for the cohort:
- Male sex at birth
- Aged <18 or >55 years of age
- BMI <30 kg/m^2

- Not able to read and/or write Dutch
- Undergoing a revisional or secondary bariatric procedure (excluding previous gastric banding)
- Malnutrition due to other chronic condition, specifically malignancy, substance abuse
- (mental) condition that makes it impossible to fill out a questionnaire correctly.

Additional criteria for the (integrated) birth cohort:
- Aged <18 or >45 years of age
- >25 weeks of gestation
- Multiple pregnancy
- Reversal of the bariatric procedure

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-08-2024
Enrollment:	1150
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-08-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL86647.091.24