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Calcium supplementation during pregnancy in low-intake populations

Submission date	Recruitment status	[ ] Prospectively registered
19/03/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/04/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/11/2022	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WHO/HRP ID 98295

Study information

Scientific Title
Calcium supplementation during pregnancy in low-intake populations

Study objectives
The purpose of this trial was to determine whether calcium supplementation of pregnant women with low calcium intake reduces pre-eclampsia and preterm delivery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial was approved by:
1. The Scientific and Ethical Review Group at UNDP/UNFPA/WHO/World Bank Special Programme for Research, Development and Research Training in Human Reproduction
2. The WHO Secretariat Committee for Research into Human Subjects
3. The Institutional Review Boards of participating centres

Study design
Multicentre double blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pre-eclampsia

Interventions
Women were assigned randomly to receive:
1. Calcium-containing tablets (1.5 g/d), one tablet three times daily (at meal time, greater than 3 hours after any iron supplements)
2. Indentical placebo

Treatment continued from enrolment to delivery. Treatment was discontinued when magnesium sulphate therapy was initiated to treat pre-eclampsia or when nephrolithiasis was diagnosed, but not when pre-eclampsia or hypertension was diagnosed.

Intervention Type

Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Calcium supplementation

Primary outcome measure
1. Primary maternal outcome: incidence of preeclampsia and/or eclampsia
2. Primary neonatal outcome: preterm delivery

Secondary outcome measures
1. Early preterm delivery (less than 32 weeks of gestation)
2. Term low birth weight (less than 2500 g; greater than or equal to 37 weeks of gestation)
3. Hospitalisation of greater than 2 days
4. Greater than or equal to 7 days in the neonatal intensive care unit
5. Foetal, neonatal, and perinatal death

Overall study start date
01/11/2001

Completion date
01/06/2003

Eligibility

Key inclusion criteria
1. Nulliparous pregnant women less than 20 weeks gestation
2. Living in low calcium intake areas

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
8500

Total final enrolment
8325

Key exclusion criteria

1. The presence of blood pressure greater than 140 and/or 90 mmHg at first antenatal visit
2. A history of chronic hypertension or renal disease
3. A history or signs and/or symptoms of nephrolithiasis, parathyroid disorders, and diseases that require digoxin, phenytoin, or tetracycline therapy

Date of first enrolment
01/11/2001

Date of final enrolment
01/06/2003

Locations

Countries of recruitment
Argentina

Egypt

India

Peru

South Africa

Switzerland

Viet Nam

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
UNDP/UNFPA/WHO/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction

Sponsor details
World Health Organization
20 Avenue Appia

Geneva-27
Switzerland
CH-1211

Sponsor type
Research organisation

Website
http://www.who.int/reproductive-health/hrp/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
United Nations Development Programme (UNDP)/United Nations Population Fund (UNFPA)/World Health Organization (WHO)/World Bank - Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/03/2006		Yes	No