ISRCTN72654148 https://doi.org/10.1186/ISRCTN72654148

MACS: Multiple Courses of Antenatal Corticosteroids for Preterm Birth Study

Submission date 09/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/02/2004	**Overall study status** Completed	
Last Edited 16/08/2011	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.utoronto.ca/macs

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00187382

Secondary identifying numbers

MCT-38142 (for MACS-5 follow up: MCT-78775)

Study information

Scientific Title

Acronym
MACS

Study objectives
In women at 26 to 30 weeks gestation who are at increased risk for preterm birth and remain undelivered 14 to 21 days following a single course of Antenatal CorticoSteroids (ACS), are multiple courses of ACS every 14 days until 33 weeks effective in reducing the risk of perinatal or neonatal mortality or significant neonatal morbidity, compared to placebo?

MACS-5: A five year follow-up of Multiple Courses of Antenatal Corticosteroids for Preterm Birth Study -
A follow up study was added to this trial in 2006 called MACS-5 (all details pertaining to this follow up only will be headed with the title MACS-5) with the hypothesis that the above will reduce the risk of death, or severe disability in neuromotor, neurosensory, or neurocognitive function, in children at five years of age.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of Sunnybrook & Women's College Health Sciences Centre, Toronto, Ontario, Canada, 26 April 2001

MACS-5:
Research Ethics Board of Sunnybrook & Womens College Health Science Centre, Toronto, Ontario, Canada, 6 July 2005; Ethics approvals for centres in other countries are pending

Study design
Multicentre, multinational, two-arms randomised parallel trial, with study participant, investigator, caregiver, outcome assessor and data analysts blinded.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Patient information can be found on the website at: http://www.utoronto.ca/miru/macs/

Health condition(s) or problem(s) studied
Pregnancies at increased risk of preterm birth

Interventions
1. Betamethasone (Celestone Soluspan):
Two doses, 12mg per dose, given IntraMuscular (IM) 24 hours apart - if risk of preterm birth continues, this will be repeated every 14 days until 33 completed weeks gestation.

2. Placebo:
Matching placebo of active treatment containing a dilute concentration of aluminum monostearate. Two doses, 12mg per dose, given IM 24 hours apart; if risk of preterm birth continues, this will be repeated every 14 days until 33 completed weeks gestation.

The contact for scientific queries for MACS-5 is:
Dr Elizabeth Vagi Asztalos
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The contact for public queries for the MACS-5 trial is:
Edna Kavuma
MACS-5 Coordinator
Maternal Infant and Reproductive Health Research Unit (MIRU)
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Telephone: 416-351-3818
Email: macs@sw.ca

The sponsor for the MACS-5 trial is:
Sunnybrook and Womens Health Sciences Centre
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This trial has now finished recruiting, and the follow up MACS-5 will be completed on 31st December 2011.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Antenatal corticosteroids

Primary outcome measure
Perinatal or neonatal mortality or serious neonatal morbidity (stillbirth or neonatal death; one or more of Respiratory Distress Syndrome [RDS], BronchoPulmonary Dysplasia [BPD], IntraVentricular Haemorrhage [IVH] grade III or IV, Cystic Peri-Ventricular Leucomalacia [PVL], Necrotizing EnteroColitis [NEC]) during the first 28 days of life or prior to hospital discharge, whichever is later.

MACS-5:
Primary outcome measured at five years of age of a child consisting of:
1. Death or impaired neuromotor (non-ambulatory cerebral palsy) or neurosensory function (blindness, deafness or need for visual or hearing aids), assessed by clinical exam
2. Abnormal attention, memory, or behaviour, assessed by parent administered questionnaire incorporating the Child Behaviour Checklist (1½ to 5) and the Behaviour Rating Inventory of Executive Function (Preschool version)

Secondary outcome measures
1. Death or neurological impairment (one or more of death, Cerebral Palsy [CP], Bayley Scales of Infant Development [BSID-II], Mental Development Index [MDI] less than 70).
2. Time point of measurement 18-24 months corrected gestational age.

MACS-5:
Measured at 5 years of age:
1. Measure of growth and blood pressure (height, weight, head circumference, systolic and diastolic Blood Pressure [BP]); assessed by clinical exam.
2. For children in English-speaking centres: intelligence and visual motor, visual spatial, and language skills; assessed by certified psychologists using the Weschler Preschool and Primary Intelligence Scale for Children - Third Edition (WPSSI-III), The Developmental Test of Visual Motor Integration - Fifth Edition (VMI) and Peabody Picture Vocabulary Test - Third Edition (PPVT-III).

Overall study start date
01/01/2004

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Women who have previously received one completed course of ACS, 14 to 21 days ago, and continue to be at increased risk of preterm birth
2. Women of child-bearing age; their children from birth to 24 months corrected gestational age, either sex
3. Gestational age more than or equal to 26 weeks of gestation and less than 30 completed weeks

4. Women at 25 to 32 weeks gestation who remain at increased risk of preterm birth 14 to 21 days after a single course of antenatal corticosteroids

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1900 (1858 participated in the MACS-5 follow up)

Key exclusion criteria
1. Women requiring chronic doses of corticosteroids secondary to medical conditions
2. Women with a contraindication to corticoosteroids
3. Women with clinical evidence of chorioamnionitis (temperature more than or equal to 38°C)
4. Known lethal congenital anomaly (e.g. anencephaly) in any fetus
5. First course of ACS given prior to 23 weeks
6. Previous participation in MACS

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Argentina

Bolivia

Brazil

Canada

Chile

China

Colombia

Denmark

Germany

Hungary

Israel

Jordan

Netherlands

Peru

Poland

Russian Federation

Spain

Switzerland

United Kingdom

United States of America

Study participating centre
790 Bay Street, 7th Floor
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Sponsor information

Organisation
University of Toronto Faculty of Medicine Research Office (Canada)

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Sponsor type
University/education

Website
http://www.medresearch.utoronto.ca/fmro_about.html

ROR
https://ror.org/03dbr7087

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-38142) (for MACS-5 follow up: MCT-78775)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	20/12/2008		Yes	No