

# MACS: Multiple Courses of Antenatal Corticosteroids for Preterm Birth Study

<b>Submission date</b> 09/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/02/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/08/2011	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00187382

**Protocol serial number**  
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

## **Primary study design**

Interventional

## **Study design**

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

## **Study type(s)**

Treatment

## **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  
Sunnybrook Health Sciences Centre  
Toronto, Ontario  
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Telephone: 416-323-6266  
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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)  
7th Floor  
790 Bay Street  
Toronto, Ontario  
Canada  
Telephone: 416-351-3818  
Email: macs@sw.ca

The sponsor for the MACS-5 trial is:

Sunnybrook and Womens Health Sciences Centre  
c/o Leslie Boehm, Director of Research Administration  
S-130 2075 Bayview Avenue  
Toronto, Ontario  
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Tel: 416-480-5720  
Email: leslie.boehm@sw.ca

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(s)**

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)

### **Key secondary outcome(s)**

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 (WPPSI-III), The Developmental Test of Visual Motor Integration - Fifth Edition (VMI) and Peabody Picture Vocabulary Test - Third Edition (PPVT-III).

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

1. Women requiring chronic doses of corticosteroids secondary to medical conditions
2. Women with a contraindication to corticosteroids

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**

United Kingdom

Argentina

Bolivia

Brazil

Canada

Chile

China

Colombia

Denmark

Germany

Hungary

Israel

Jordan

Netherlands

Peru

Poland

Russian Federation

Spain

Switzerland

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)

### 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

### 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?
<a href="#">Results article</a>	results	20/12/2008		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes

