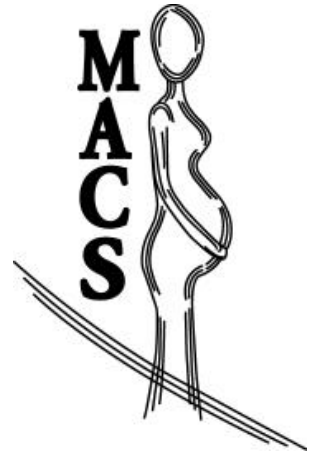


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MACS news



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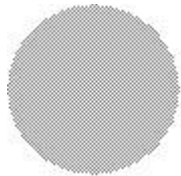
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It is very important to the success of the trial that all centres planning to take part begin to recruit as soon as possible.

Can your centre join the "ready to recruit" list next month? We look forward to adding your name.



Need to talk to us? We are easy to reach at any of the contact points shown above.

The trial begins - 4 centres now ready to recruit:

USA: Albany Medical Center

CANADA: Royal University, Saskatoon

DENMARK: Aarhus University

ISRAEL: Rabin Medical Center, Petach Tikva

The randomisation service was opened on February 15. To date there are 4 active sites that have returned all of their completed paperwork and have been sent start-up packages and supplies of study drug. We are all eagerly awaiting the first recruit...

Congratulations!

Centres pursuing Ethics/IRB approval:

CANADA:
Royal Alexandra, Edmonton
IWK Grace, Halifax
Ste-Justine, Montreal
Regina General, Regina
CHUS Fleurimont, Sherbrooke
Sunnybrook & Women's College, Toronto
Mount Sinai, Toronto
Children's & Women's of BC, Vancouver
St Boniface General, Winnipeg

USA
University of New Mexico, Albuquerque
University of Michigan, Ann Arbor
Jacobi, Bronx
Albert Einstein COM, Bronx
Maimonides, Brooklyn
Des Moines Perinatal Center, Des Moines
University of Iowa, Iowa City
Maricopa, Phoenix. University, Lausanne

ISRAEL:
Haemek, Afula
Soroka, Beer Sheva
Ma'ayne Hayeshua, Bnei Brak
Bnai Zion, Haifa
Meir, Kfar-Saba
Poriya, Tiberias

NETHERLANDS:
Atrium, Heerlen

SWITZERLAND: Lausanne

Another 60+ centres world-wide are considering participation.



Protocol revisions

We have recently made some revisions to the MACS protocol and submitted the changes to the University of Toronto. We will be sending copies to each active or interested site shortly.



The major difference between the July 2000 version and the current one is that we have extended the treatment period from ending at 33^{0/7} weeks gestational age to ending at 33^{6/7} weeks. We did this based on information received from collaborators during the November 2000 meeting in Toronto. The investigators at that meeting felt that the extension to 33^{6/7} weeks was more in keeping with their current practice patterns, and also with the original NIH consensus guidelines for antenatal corticosteroids. Other changes are minor and have generally been made to increase clarity.



The patient information sheet has also been modified in two ways. First, we have deleted the statement regarding a possible association of multiple courses of antenatal corticosteroids and necrotising enterocolitis. This association was initially suggested by a group of investigators (Abbasi et al) in abstract form. However, when the completed analysis was published in full, no association was found. (Abbasi S, Hirsch D, Davis J, Tolosa J, Stouffer N, Debbs, R et al. *Effect of single versus multiple courses of antenatal corticosteroids on maternal and neonatal outcome*. Am J Obstet Gynecol 2000;182:1243-9.)



Second, we have indicated that we may want to contact participants again, after the two year assessment. This was added because of a general expression of support among collaborators for extended follow-up. To date no specific plans have been made.



MACS has now received regulatory approval from Health Canada, in addition to the FDA waiver obtained in the USA. If you are located outside of Canada or the USA, remember to consider whether government approval may be necessary in order for you to participate.