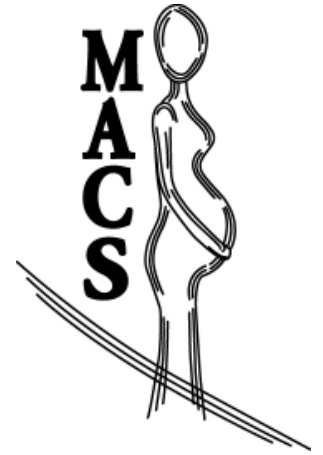


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MACS news



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Overall Total:121

Total this month: 17

Way to go!

Well done to all of you for your hard work recruiting this month!

This is a new monthly record of 17 for May!

Thank you all for your efforts.

Let's keep these numbers moving up in June!



Also enclosed in this issue - notes from the "success stories" presented by several collaborators at the recent meeting in Toronto.

Protocol revisions

The Steering Committee has suggested that we make some revisions to the MACS protocol, and details are provided below. The most notable change is a widening of the period of eligibility for enrolment, as we have had input from collaborators that this revision would bring the MACS protocol more in line with current practice in many centres. Once the change is approved, you will be able to recruit patients between 25^{0/7} and 32^{6/7} weeks gestational age (as long as it is 14-21 days after their first non-study course of corticosteroids).

We have submitted the changes to the Research Ethics Board at the University of Toronto and we will send you the new protocol as soon as it is approved. In the meantime, we are including a copy of the revised patient information sheet which you may be able to submit to your local Ethics Committee/IRB now.

The changes to note:

Section 2.3 Selection Criteria for Participants - page 7

Replace 26^{0/7}-30^{6/7} weeks gestation with 25^{0/7}-32^{6/7} weeks gestation:

The target population is women at increased risk of preterm birth †, at 25^{0/7}-32^{6/7} weeks gestation, who have received one course of ACS, 14-21 days ago. Women will not be eligible until they reach 25^{0/7} weeks gestation, as we do not expect an initial course of ACS to be given prior to 23^{0/7} weeks gestation. Women who receive an initial course of antenatal corticosteroids prior to 23^{0/7} weeks gestational age will be considered ineligible.

Other occurrences of the specification of gestational age 26^{0/7}-30^{6/7} in Section 2.1 (Primary, Secondary, and Other Research Questions) and Section 2.2, will also be revised.

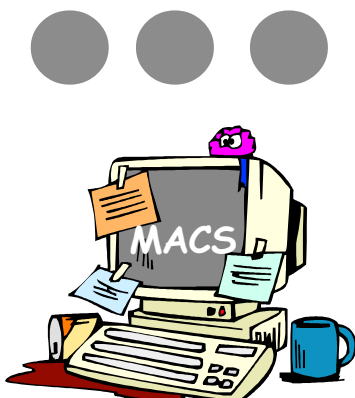
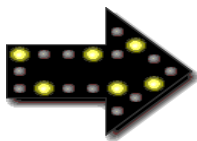
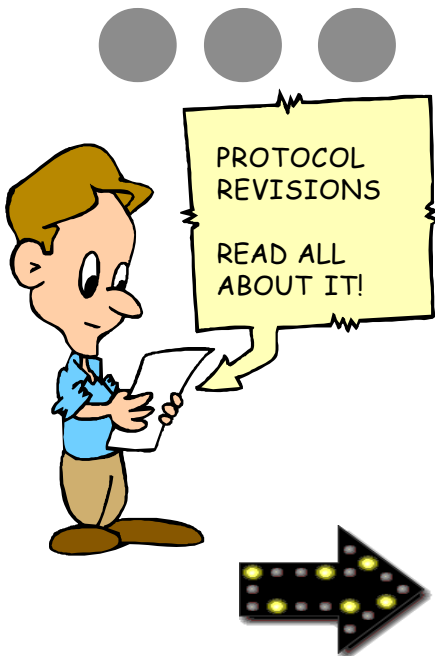
Section 2.7.3 Both Groups - page 10

Replace the sentence beginning "If infants are born less than 1500 grams..." with the following:

If infants are born less than 1500 grams, centres should arrange a cranial ultrasound prior to hospital discharge to look for evidence of IVH and cystic periventricular leukomalacia (PVL). We recommend at least one cranial ultrasound be performed between day 1 and 3, and on day 7 and day 21. Centres are also encouraged to perform ophthalmologic exams to look for retinopathy of prematurity (ROP).



Please note that we have a new email address to make it even easier to reach us: macs@swchsc.on.ca (our personal email addresses will still work as well)





Recruitment

(Projected sample size of 1900 by July 2004)

as of May 31, 2002

Annual Goal	Apr – Dec	Jan - Mar	Apr	May	Jun	Grand Total
	01	02	02	02	02	

COUNTRY

CANADA	110	29	11	6	8		54
ISRAEL	113	20	7	1	5		33
DENMARK	15	9	3	1			13
USA	13	8			1		9
SWITZERLAND	10	3	2		1		6
HUNGARY	9		3	1	2		6
Total	270	69	26	9	17		121

CENTRES BY COUNTRY

(shaded area is prior to start-up)

CANADA							
Mount Sinai, Toronto	23	9	3	1	1		14
Royal University, Saskatoon	13	8	2	1	3		14
Children's & Women's, Vancouver	24	7	1	1			9
CHUS (Fleurimont), Sherbrooke	10	3	4	1			8
Royal Alexandra, Edmonton	14	2		2	1		5
Regina General, Regina	10		1				1
IWK Health Centre, Halifax	16				3		3

ISRAEL							
Rabin, Petach Tikva	26	9	1		1		11
Ma'ayne Hayeshua, Bnei Brak	16	7	1				8
Bnai Zion, Haifa	13	3			2		5
Soroka, Beer Sheva	38	1	1		1		3
Haemek, Afula	13		4		1		5
Poriya Government, Tiberias	7			1			1

DENMARK							
Aarhus University, Aarhus	15	9	3	1			13

USA							
Montefiore, Bronx	13	7			1		8
Albany (No longer recruiting)	—	1					1



Recruitment

(Projected sample size of 1900 by July 2004)

Annual Goal	Apr - Dec 01	Jan - Mar 02	Apr 02	May 02	Jun 02	Grand Total
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SWITZERLAND						
CHU Vaudois, Lausanne	5	3	2			5
Univ Women's Hospital, Basel	5				1	1

HUNGARY						
University of Debrecen, Debrecen	9		3	1	2	6

Centres awaiting first patient: [COUNTRY: Hospital, City (annual goal)] [month/year start-up package sent]

CANADA: St Boniface General, *Winnipeg* (13) [11/01]; IWK Health Centre, *Halifax* (16) [12/01]; Sunnybrook & Women's College, *Toronto* (12) [12/01]. **ISRAEL:** Poriya Government, *Tiberias* (7) [05/01]; Meir, *Kfar-Saba* (18) [06/01]. **USA:** Maricopa, *Phoenix* (11)[04/01]; University of New Mexico, *Albuquerque* (12)[10/01]; Bethesda, *Cincinnati* (13) [01/02]; Good Samaritan, *Cincinnati* (18) [01/02]. **THE NETHERLANDS:** Atrium, *Heerlen* (6) [07/01].



Keep up the Good Work!

Quote of the Month: "Your actions and attitude set the atmosphere around you."