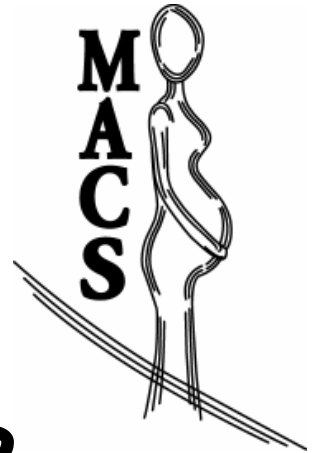


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MACS news



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Overall Total: 562

Total this month: 22

WELCOME to our newest MACS centres in two new countries!!

- Hospital Geral (Caxias do Sul, Brazil)
- Posados, (Buenos Aires, Argentina)



MUGS THIS MONTH

MACS mugs are on their way to the following centres, who have recruited 5 more women into the study:

University School of Medicine (Poznan, Poland), Research Institute at PMMH (Lodz, Poland), Medical University of Gdansk (Gdansk, Poland), Sotero del Rio (Puento Alto, Chile), Benjamin Franklin (Berlin, Germany)



If you haven't already received your Collaborators' meeting confirmation, please email macs@sw.ca to confirm your attendance.

We have made some modifications to the protocol. Below are the protocol revisions. We will be sending a copy of the revised protocol to you for submission to your local ethics committee shortly.

Section 2.3 Selection Criteria for Participants:

Inclusion Criterion

Add new inclusion criterion:

All fetus(es) must be alive at randomisation. However, in multiple gestation pregnancies, if any fetus is thought to have died prior to 13 weeks, that fetus will not be considered part of the pregnancy for the purposes of this study. For example, if a twin pregnancy is diagnosed at 8 weeks but on an ultrasound at 18 weeks only one fetus is seen, or if the dead twin fetus is so small that demise is thought to have occurred prior to 13 weeks, that pregnancy should be considered a singleton.

Section 2.7.3 Manoeuvre in both groups

New version:

All babies will be followed until 18-24 months of age (corrected for gestational age at birth), at which time they will undergo a neurodevelopmental and behavioural assessment. The assessment will include an **assessment of motor function (Gross Motor Function Classification System [Palisano et al]), documentation of hospitalization, height, weight, head circumference, a clinical impression of developmental level** and a standardised neurological examination to rule out cerebral palsy (CP).⁵⁴ Personnel for the neurodevelopmental examinations will include neonatologists, general paediatricians, developmental paediatricians, or trained nurses, who are experienced in performing neurodevelopmental examinations for follow-up programs, development assessment centres &/or treatment centres for disabilities. If the test is locally available, all babies will be assessed using the revised Bayley Scales of Infant Development (BSID-II) to determine the level of mental and physical functioning (Mental Developmental Index [MDI] and Physical Developmental Index [PDI]). The BSID-II are well standardised, and have demonstrated reliability and validity.⁵⁵ If the BSID-II are not available then the results of other standardised tests **may** be accepted.

Section 2.8.1 Primary Outcome: Perinatal or neonatal mortality or significant neonatal morbidity

New version:

Respiratory Distress Syndrome (RDS): defined as requiring assisted ventilation via endotracheal tube and supplemental oxygen both within the first 24 hours of life and for a duration of greater than or equal to 24 hours and either an x-ray compatible with RDS or surfactant given between the first 2 and 24 hours of life.

Section 2.11.2 Final Analysis:

The level of statistical significance for the analysis of the primary and secondary outcomes will be **$P < 0.05$, using a 2 tailed test.**

Recruitment

(Projected sample size of 1900 by December 2004)



as of September 30, 2003

Annual Goal	Apr - Dec	Jan - Jun	Jul - Dec	Jan - June	July	Aug	Sept	Grand Total
	01	02	02	03	03	03	03	

COUNTRY

CANADA	138	29	31	36	33	6	5	1	141
POLAND	37		4	66	51	2	2	7	132
ISRAEL	143	20	22	28	28	6	5	4	113
CHILE	35			20	14	3	2	1	40
USA	60	8	3	6	11	1			29
HUNGARY	9		7	10	8		3		28
DENMARK	15	9	7	6	4			1	27
GERMANY	34			2	12	6	1	5	26
SWITZERLAND	10	3	4	2	3		2	1	15
JORDAN	23				6	1		2	9
THE NETHERLANDS	11				2				2
Total	515	69	78	176	143	25	20	22	562

CENTRES BY COUNTRY

(shaded area is prior to start-up)

CANADA									
Mount Sinai, Toronto	23	9	8	10	3	3	1		34
Royal University, Saskatoon	13	8	6	3	4				21
Royal Alexandra, Edmonton	14	2	3	5	7		1		18
Children's & Women's, Vancouver	24	7	2	3	2	1	1		16
CHUS (Fleurimont), Sherbrooke	10	3	6	3	2	1	1		16
IWK Health Centre, Halifax	16		3	2	7			1	13
Sunnybrook & Women's, Toronto	12			3	5				8
St Boniface General, Winnipeg	13		2	3	2				7
Regina General, Regina	10		1	4			1		6
North Bay General, North Bay	3				1	1			2

POLAND									
Univ School of Medicine, Poznan	18			35	17		1	4	57
Research Inst at PMMH, Lodz	14			21	17			2	40
Med University of Gdansk, Gdansk	5		4	10	17	2	1	1	35

ISRAEL									
Rabin, Petach Tikva	26	9	5	5	6		2		27
Edith Wolfson, Holon	12			8	9	1	2	2	22
Haemek, Afula	13		6	4	4	1	1	2	18
Ma'ayne Hayeshua, Bnei Brak	16	7	1		4	3			15
Soroka, Beer Sheva	38	1	5	7	1				14
Bnai Zion, Haifa	13	3	3		4	1			11
Poriya Government, Tiberias	7		1	2					3
Meir, Kfar-Saba	18		1	2					3



Recruitment

(Projected sample size of 1900 by December 2004)

Annual Goal	Apr - Dec	Jan - Jun	Jul - Dec	Jan - May	July	Aug	Sept	Grand Total
	01	02	02	03	03	03	03	

CHILE									
Sotero del Rio, Puente Alto	26			16	6	1	2	1	25
Universidad Católica, Santiago	9			4	8	2			14

USA									
Montefiore, Bronx	13	7	2	4	7	1			21
Bethesda, Cincinnati	13		1	1	1				3
Good Samaritan, Cincinnati	18			1	1				2
Baystate Medical Center, Springfield	16				2				2
Albany (No longer recruiting)	—	1							1

HUNGARY									
University of Debrecen, Debrecen	9		7	10	8		3		28

DENMARK									
Aarhus University, Aarhus	15	9	7	6	4			1	27

GERMANY									
Klinikum Nurnburg Sud, Nurnburg	15			2	9	1	1		13
Benjamin Franklin, Berlin	15				3	4		3	10
TU Munchen, Munchen	4					1			1
University of Marburg, Marburg	4							2	2

SWITZERLAND									
Univ Women's Hospital, Basel	5		1	1	3		2	1	8
CHU Vaudois, Lausanne	5	3	3	1					7

JORDAN									
Islamic, Amman	23				6	1		2	9

THE NETHERLANDS									
Atrium, Heerlen	6				1				1
Academisch Ziekenhuis, Maastricht	5				1				1

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

USA: Maricopa, *Phoenix* (11) [04/01]; Medical University of South Carolina, *Charleston* (7) [06/02]. **CHINA**: Peace Maternity, *Shanghai* (18) [02/03]. **GERMANY**: MHH Hannover, *Hannover* (5) [06/03]; Dr Horst-Schmidt-Kliniken, *Wiesbaden* (8) [08/03]; St. Hedwig Hospital, *Regensburg* (4) [07/03]. **ISRAEL**: Sheba Medical Centre, *Ramat-Gan* (22) [07/03]. **SPAIN**: Hospital Clinic, *Barcelona* (10) [07/03]. **UK**: Queen Elizabeth Hospital, *King's Lynn* (5) [08/03]. **BRAZIL**: Hospital Geral, *Caxias do Sul* (5) [09/03].



Keep up the Good Work!

Quote of the Month:

“The real secret of success is enthusiasm”

-Walter Chrysler