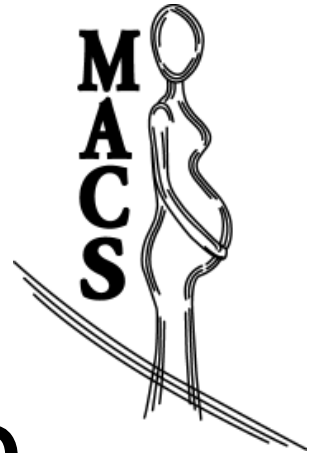


April 30, 2004  
Volume 5, Issue 4

# MACS news



**Data Coordinating Centre:**

**MIRU**

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## Overall Total: 780

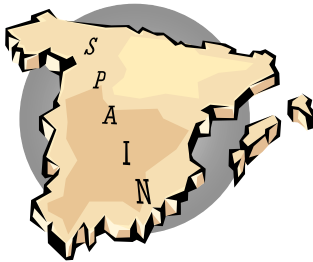
### Total this month: 39

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### Site Visits

Dr Kellie Murphy and Emily Karahalios visited University of Barcelona Hospital Clinic in Spain and Assisi Hospital in Italy this month. Kellie and Emily would like to thank all of the collaborators for welcoming them to Spain and Italy and a special thank you to Dr Montse Palacio and Ms Sonia Pisa from Spain as well as Dr Roberto Luzietti from Italy.

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A surprise gift is going out to the following centres that recruited 2 or more patients into MACS in the month of April:

**Mount Sinai** (*Toronto, Canada*)

**CHUS Fleurimont** (*Sherbrooke, Canada*)

**Research Institute at Polish Mothers Memorial** (*Lodz, Poland*)

**Haemek** (*Afula, Israel*)

**Sotero del Rio** (*Puente Alto, Chile*)

**Universidad Catolica** (*Santiago, Chile*)

**Benjamin Franklin** (*Berlin, Germany*)

**University of Debrecen** (*Debrecen, Hungary*)

**CEMIYA** (*Cali, Colombia*)



### MUGS THIS MONTH

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

Mount Sinai (*Toronto, Canada*)  
 Research Institute at PMMH (*Lodz, Poland*)  
 Sotero del Rio (*Puente Alto, Chile*)  
 Klinikum Nurnburg Sud (*Nurnburg, Germany*)  
 CEMIYA (*Cali, Colombia*)

Also a mug is going out to North Bay General for reaching their annual goal for 2004! Congratulations and keep up the great work!

We would like to remind all of our centres using English forms to discard any non-NCR forms!

### **Recruitment Tips:**

We would like to thank Dr Ricardo Gomez from Sotero del Rio, Puente Alto, Chile for providing us with the following recruitment tips:

- As a MACS investigator you may want to speak with hesitant patients yourself in order to encourage women to join MACS.
- In order to ensure that women are receiving subsequent courses of study drug the MACS investigator or coordinator might consider visiting the patient at home to administer the study drug.



as of April 30, 2004

Annual Goal	Apr - Dec 2001	Jan - Dec 2002	Jan - Jun 2003	Jul - Dec 2003	Jan 2004	Feb 2004	Mar 2004	Apr 2004	Grand Total
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**COUNTRY**

CANADA	142	29	67	33	33	9	7	13	6	197
POLAND	37		70	51	25	3	4	2	3	158
ISRAEL	165	20	50	28	28	14	2	2	3	147
CHILE	61		20	14	9	5	1	2	7	58
GERMANY	65		2	12	21	2	2	1	5	45
HUNGARY	9		17	8	6	2	2		3	38
USA	50	8	9	11	3	1	1		2	35
DENMARK	15	9	13	4	1		3			30
SWITZERLAND	10	3	6	3	5	1	2			20
JORDAN	23			6	6	3				15
COLOMBIA	26							1	6	7
ARGENTINA	39				2	1		3	1	7
BRAZIL	5				3		1	1	1	6
THE NETHERLANDS	11			2	3	1				6
RUSSIAN FEDERATION	5				1		1	1	1	4
SPAIN	10				3	1				4
UK	5				1	1				2
CHINA	18								1	1
<b>Total</b>	<b>696</b>	<b>69</b>	<b>254</b>	<b>172</b>	<b>150</b>	<b>44</b>	<b>26</b>	<b>26</b>	<b>39</b>	<b>780</b>

**CENTRES BY COUNTRY**

(Shaded area is prior to start-up)

**CANADA**

Mount Sinai, Toronto	23	9	18	3	8	2	3	5	2	50
Royal Alexandra, Edmonton	14	2	8	7	4		1	1	1	24
Royal University, Saskatoon	13	8	9	4	2					23
CHUS Fleurimont, Sherbrooke	10	3	9	2	3		1	3	2	23
IWK Health Centre, Halifax	16		5	7	5	1	1			19
BC Women's, Vancouver	24	7	5	2	2			1		17
St Boniface General, Winnipeg	13		5	2	4	3	1			15
Regina General, Regina	10		5		1	2		1		9
North Bay General, North Bay	3			1	4	1		1	1	8
Sunnybrook & Women's College, Toronto	12		3	5						8
Dr Everett Chalmers Regional, Fredericton	4							1		1

**POLAND**

Univ School of Medicine, Poznan	18		35	17	13		1	2	1	69
Res Inst at Polish Mothers Memorial, Lodz	14		21	17	2	3			2	45
Med Univ of Gdansk, Gdansk	5		14	17	10		3			44

**ISRAEL**

Rabin, Petach Tikva	26	9	10	6	2	2				29
Haemek, Afula	13		10	4	7	3	2		2	28
Edith Wolfson, Holon	12		8	9	6	2				25
Ma'ayney Hayeshua, Bnei Brak	16	7	1	4	5	1			1	19
Meir, Kfar-Saba	18		3		5	6		1		15
Soroka, Beer Sheva	38	1	12	1						14
Bnai Zion, Haifa	13	3	3	4	1			1		12
Poriya Government, Tiberias	7		3							3
Sheba Medical Center, Ramat-Gan	22				2					2

**CHILE**

Sotero del Rio, Puente Alto	26		16	6	6	5	1	2	4	40
Universidad Catolica, Santiago	9		4	8	3				2	17
Hospital Clinico San Borja Arriaran, Santiago	26								1	1

**GERMANY**

Klinikum Nurnburg Sud, Nurnburg	15		2	9	6	1		1	1	20
Benjamin Franklin, Berlin	15			3	7				2	12
St Hedwig Hospital, Regensburg	4				2	1				3

	Annual Goal	Apr - Dec 2001	Jan - Dec 2002	Jan - Jun 2003	Jul - Dec 2003	Jan 2004	Feb 2004	Mar 2004	Apr 2004	Grand Total
University of Marburg, Marburg	4				2		1			3
<b>GERMANY</b>										
University of Leipzig, Leipzig	5				2		1			3
University Women's Hospital, Homburg	5								1	1
MHH Hannover, Hannover	5				1					1
TU Munchen, Munchen	4				1					1
Dr Horst-Schmidt-Kliniken, Wiesbaden	8								1	1

#### HUNGARY

University of Debrecen, Debrecen	9		17	8	6	2	2		3	38
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#### USA

Montefiore Medical Center, Bronx	13	7	6	7	2		1			23
Bethesda, Cincinnati	13		2	1	1	1				5
Good Samaritan (No longer recruiting)	0		1	1						2
Baystate (No longer recruiting)	0			2						2
Winthrop, Mineola	16								1	1
Albany (No longer recruiting)	0	1								1
University of Illinois, Chicago	8								1	1

#### DENMARK

Aarhus University, Aarhus	15	9	13	4	1		3			30
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#### SWITZERLAND

University Women's Hospital, Basel	5		2	3	5	1	2			13
CHU Vaudois, Lausanne	5	3	4							7

#### JORDAN

Islamic, Amman	23			6	6	3				15
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#### COLOMBIA

CEMIYA, Cali	26							1	6	7
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#### ARGENTINA

Posadas, Buenos Aires	13				2	1		2	1	6
LC Lagomaggiore, Mendoza	26							1		1

#### BRAZIL

Hospital Geral, Caxias do Sul	5				3		1	1	1	6
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#### THE NETHERLANDS

Academisch Ziekenhuis, Maastricht	5			1	3	1				5
Atrium, Heerlen	6			1						1

#### RUSSIAN FEDERATION

Research Centre of Obs, Gyn & Perinatology, Moscow	5				1		1	1	1	4
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#### SPAIN

UB Hospital Clinic, Barcelona	10				3	1				4
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#### UK

The Queen Elizabeth Hospital, King's Lynn	5				1	1				2
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#### CHINA

Peace Maternity, Shanghai	18								1	1
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Centres awaiting first patient: [COUNTRY: Hospital, City (annual goal)] [month/year start-up package sent]

**GERMANY:** Helios Klinikum, *Erfurt* (5) [11/03]. **UK:** Forth Park, *Kirkcaldy* (10) [10/03]; Royal Free, *London* (9) [04/04]. **ISRAEL:** Hadassah Ein Kerem, *Jerusalem* (13) [11/03]. **SWITZERLAND:** University Hospital, *Zurich* (6) [03/04]. **ARGENTINA:** Hospital Sarda, *Buenos Aires* (22) [04/04]; Hospital Penna, *Bahia Blanca* (10) [03/04].



Quote of the Month:

“The only place success comes before work is in the dictionary.”

Donald Kendall

**Keep up the Good Work!**

## 2 Year Follow-up of MACS Babies

The status of the MACS 2-year Follow-up is displayed in the following table for centres that recruited patients. Centres are listed according to the total number of recruits by country and centre. See below for the number of follow-up assessments performed by your centre!



**We have completed over 80% of the follow up for 2001. CONGRATULATIONS!**

Follow-Up Status	2001		2002		2003		2004		Totals	
	# Recruited	# Complete Follow-Up	# Recruited	# Complete Follow-Up	# Recruited	# Complete Follow-Up	# Recruited	# Complete Follow-Up	# Recruited	# Complete Follow-Up
<b>As of April 2004</b>										
<b>COUNTRY</b>										
CANADA	29	28	67	14	66		35		197	42
POLAND			70	1	76		12		158	1
ISRAEL	20	15	50	8	56		21		147	23
CHILE			20		23		15		58	
GERMANY			2		33		10		45	
HUNGARY			17		14		7		38	
USA	8	7	9		14		4		35	7
DENMARK	9	9	13		5		3		30	9
SWITZERLAND	3		6		8		3		20	
JORDAN					12		3		15	
COLOMBIA							7		7	
ARGENTINA					2		5		7	
THE NETHERLANDS					5		1		6	
BRAZIL					3		3		6	
RUSSIAN FEDERATION					1		3		4	
SPAIN					3		1		4	
UK					1		1		2	
CHINA							1		1	
<b>Total</b>	<b>69</b>	<b>59</b>	<b>254</b>	<b>23</b>	<b>322</b>		<b>135</b>		<b>780</b>	<b>82</b>
		86%		9%						11%

### CENTRES BY COUNTRY

(Shaded area is prior to start-up)

#### CANADA

Mount Sinai, Toronto	9	9	18	2	11		12		50	11
Royal Alexandra, Edmonton	2	2	8	4	11		3		24	6
CHUS Fleurimont, Sherbrooke	3	3	9	5	5		6		23	8
Royal University, Saskatoon	8	7	9		6				23	7
IWK Health Centre, Halifax			5	1	12		2		19	1
BC Women's, Vancouver	7	7	5	2	4		1		17	9
St Boniface General, Winnipeg			5		6		4		15	
Regina General, Regina			5		1		3		9	
North Bay General, North Bay					5		3		8	
Sunnybrook & Women's College, Toronto			3		5				8	
Dr Everett Chalmers Regional, Fredericton							1		1	

#### POLAND

Univ School of Medicine, Poznan			35	1	30		4		69	1
Res Inst at Polish Mothers Memorial, Lodz			21		19		5		45	
Med Univ of Gdansk, Gdansk			14		27		3		44	

#### ISRAEL

Rabin, Petach Tikva	9	7	10		8		2		29	7
Haemek, Afula			10	1	11		7		28	1
Edith Wolfson, Holon			8		15		2		25	
Ma'ayne Hayeshua, Bnei Brak	7	5	1		9		2		19	5
Meir, Kfar-Saba			3		5		7		15	
Soroka, Beer Sheva	1	1	12	6	1				14	7
Bnai Zion, Haifa	3	2	3	1	5		1		12	3
Poriya Government, Tiberias			3						3	
Sheba Medical Center, Ramat-Gan					2				2	

#### CHILE

Sotero del Rio, Puente Alto			16		12		12		40	
Universidad Catolica, Santiago			4		11		2		17	
Hospital Clinico San Borja Arriaran, Santiago							1		1	

Follow-Up Status	2001		2002		2003		2004		Totals	
	#Recruited	# Complete Follow-Up	#Recruited	# Complete Follow-Up	#Recruited	# Complete Follow-Up	#Recruited	# Complete Follow-Up	#Recruited	# Complete Follow-Up

As of April 2004

**GERMANY**

Klinikum Nurnburg Sud, Nurnburg			2		15		3		20	
Benjamin Franklin, Berlin					10		2		12	
University of Leipzig, Leipzig					2		1		3	
University of Marburg, Marburg					2		1		3	
St Hedwig Hospital, Regensburg					2		1		3	
University Women's Hospital, Homburg							1		1	
MHH Hannover, Hannover					1				1	
TU Munchen, Munchen					1				1	
Dr Horst-Schmidt-Kliniken, Wiesbaden							1		1	

**HUNGARY**

University of Debrecen, Debrecen			17		14		7		38	
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**USA**

Montefiore Medical Center, Bronx	7	7	6		9		1		23	7
Bethesda, Cincinnati			2		2		1		5	
Baystate Medical Center, Springfield					2				2	
Good Samaritan, Cincinnati			1		1				2	
Winthrop, Mineola							1		1	
Albany (No longer recruiting)	1								1	
University of Illinois, Chicago							1		1	

**DENMARK**

Aarhus University, Aarhus	9	9	13		5		3		30	9
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**SWITZERLAND**

University Women's Hospital, Basel			2		8		3		13	
CHU Vaudois, Lausanne	3		4						7	

**JORDAN**

Islamic, Amman					12		3		15	
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**COLOMBIA**

CEMIYA, Cali							7		7	
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**ARGENTINA**

Posadas, Buenos Aires					2		4		6	
LC Lagomaggiore, Mendoza							1		1	

**BRAZIL**

Hospital Geral, Caxias do Sul					3		3		6	
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**THE NETHERLANDS**

Academisch Ziekenhuis, Maastricht					4		1		5	
Atrium, Heerlen					1				1	

**SPAIN**

UB Hospital Clinic, Barcelona					3		1		4	
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**RUSSIAN FEDERATION**

Research Centre of Obs, Gyn & Perinatology, Moscow					1		3		4	
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**UK**

The Queen Elizabeth Hospital, King's Lynn					1		1		2	
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**CHINA**

Peace Maternity, Shanghai							1		1	
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## **MACS Data Safety Monitoring Board (DSMB)**

### **Statement to collaborators:**

On April 6<sup>th</sup> 2004 the MACS Data Safety Monitoring Board met by teleconference to discuss the ongoing state of the trial and to decide whether a recent decision to stop recruitment by the NICHD single v. multiple courses of steroid trial should influence the conduct of MACS. We had access to the published abstract (Am J Obstet Gynecol Dec 2003 S56 SMFM abstracts) as well as a response from the NICHD investigators to a series of questions posed to them by us concerning their reasons for stopping the NICHD trial. The NICHD were kind enough to respond in considerable detail to all our questions.

We congratulate the MACS trialists on having designed, and for conducting, an exemplary trial. We observed nothing in the NICHD actions or interim trial results which should cause concern for the MACS trial. We recommended no change to the preplanned strategy for monitoring the trial. Indeed, the NICHD group concludes in its abstract that “Further investigation of limited repeated steroid administration to women at high risk for early preterm birth is warranted”. We believe that this is best carried out by continuing and increasing recruitment to the MACS trial.

#### **MACS DSMB members:**

Michael B. Bracken, Chair  
Center for Perinatal, Pediatric and Environmental Epidemiology  
Yale University

Patricia Crowley  
Coombe Women’s Hospital  
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Allan Donner  
Department of Epidemiology and Biostatistics  
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Lelia Duley  
Resource Center for Randomised Trials  
Institute of Health Sciences  
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Jon Tyson  
Center for Population and Evidence-Based Medicine  
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