

Noticias News Nouvelles

Volume 5 Issue 4

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University of Toronto Maternal, Infant and Reproductive Health Research Unit at The Centre for Research in Women's Health

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Total recruited in April: 65 Overall Total: 1340

RECRUITMENT

We are almost ¹/₂ way there. Please keep up your recruitment efforts. Obstetricians around the world are anxiously awaiting the results of The Term Breech Trial. They are counting on us. Your enthusiasm will rub off on your colleagues and their patients.

INTERIM ANALYSIS

We still have some important primary outcome data that we are checking with centres, but we should be ready soon to proceed to the interim analysis soon. We will keep you posted.



COMPLIANCE WITH MODE OF DELIVERY

Please don't forget to make sure the woman is truly eligible. If you have any doubts about this, don't randomize! If the woman is in labour, make sure you can proceed directly to Caesarean section (should the woman be allocated to that group), and if you can't (e.g. the operating room is not available), don't randomize! Recruitment is important but not at the expense of compliance with mode of delivery.

Mugs this month:

(for centres reaching or passing their annual goal)



Mona Vale, *Mona Vale*, AUSTRALIA (#2); **IOMC-Polizu**, *Bucharest*, ROMANIA (#2); **Womenš & Childrenš**, *Adelaide*, AUSTRALIA; **King George V Memorial**, *Sydney*, AUSTRALIA.

Centres recruiting for the first time:

IMI Pernambuco, Recife, BRAZIL (3 patients); Hadassah Ein Karem, Jerusalem, ISRAEL.

DATA FORMS

With our preparations for the interim analysis we have been reviewing the data more closely. A number of issues have surfaced which we are in the process of contacting you to help us resolve. There is a certain amount of variability among Term Breech Trial centres for some routine aspects of the care for women in labour and during birth. As we learn these routines, we will need to contact you less. We appreciate very much the efforts many of you are making to provide us with complete and accurate data and your efforts are clearly visible during our reviews of the data forms. We know you share with us the wish to have all the Term Breech Trial data as accurate and complete as possible.

Here are some general issues that would help us at the Data Centre.

- When the woman is admitted to hospital, the date and time should correspond to the date and time that she is admitted to either the antenatal ward or to the labour and delivery room.
- If the woman labours and delivers in the same room, mark N/A for the date and time of admission to the delivery room.
- If the woman does not have an operation (e.g. Caesarean section), mark N/A for the dates and times of admission and discharge to the operating room.
- When you indicate on the *Entry Form* that the woman has ruptured membranes, we expect the date and time of randomisation to be after the date and time of membrane rupture as noted on the *Labour & Delivery Form* (and vice versa).
- Please mark the date and time for membrane rupture even if you have to estimate it.
- When you indicate on the *Entry Form* that the woman is in active labour, we expect the date and time of randomisation to be after the date and time for the start of active labour as noted on the *Labour & Delivery Form* (and vice versa).
- If the one of the reasons for Caesarean section is 'footling breech' presentation, we expect the presentation at delivery to be a footling breech.
- If the woman has a vaginal breech delivery, we very much want to know the type of breech presentation at delivery please try to avoid marking 'breech of uncertain type'. This category was put on the forms for women having Caesarean section, where it might not be possible to distinguish between a complete breech and a footling breech presentation.
- If a woman does not have a trial of labour (N/A is marked for the start date and time for active labour), and she proceeds to Caesarean section, please do not mark 'fetal pelvic disproportion/failure to progress' or we will contact you. If the Caesarean section is because you think the baby is too big for the pelvis without allowing a trial of labour, please tick 'fetal weight estimated too big for vaginal delivery'.
- If the mother and baby are discharged on different days, please write us a note on the form itself as to why this is, or let us know that this is a normal routine in your centre; otherwise we will think you have made a mistake.
- If you have any questions about the definitions for the maternal and neonatal complications, please contact us. It is very important that these outcome data are recorded accurately.
- If the mother receives maternal antibiotics after delivery, please tick the appropriate box on the maternal complications form, but then please don't tick 'none' as well.
- We are limited at the Data Centre by the languages we can read. If your mothers write in languages other than English, please don't forget to translate the written comments on the postpartum questionnaires. Even French is a struggle for us. We very much appreciate your help with this important part of the study.



Recruitment

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UK	140	43	34	29	6	7	3	4	104
ARGENTINA	43	13	26	46	7	3	6	9	110
INDIA	45	13	18	37	7	3	3	2	84
BRAZIL	49	1	19	42	11	4	1	4	82
ISRAEL	106	15	21	25	5	4	8	2	80
AUSTRALIA	51	14	36	21		1	3	5	80
JORDAN	42	1	10	34	8	7	8	7	75
SOUTH AFRICA	41	12	28	23	2				65
CHILE	46	7	3	37	5	3	6	4	65
USA	98	16	11	22	2	2	3	2	58
ZIMBABWE	39		1	23	4	5			33
FINLAND	13	15	4	3		1			23
ROMANIA	9			2	1	4	8	6	21
POLAND	22	1	6	6		5	1	1	20
EGYPT	12		4	8	2	2	1	1	18
YUGOSLAVIA	15	5	10	1			1		17
SWITZERLAND	9	3	6	5					14
PORTUGAL	7			11		1			12
THE NETHERLANDS	5			8		2	2		12
MEXICO	12		3	5					8
GERMANY	7	1		5	1				7
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Madunea (15 00 01	Medunsa	25		23	21			1		44		

		m				<u> </u>			21
Recruiting centres s of April 30, 1999	Annual Goal	Jan-Dec 97	Jan-Jun 98	Jul-Dec 98	Jan 99	Feb 99	Mar 99	<u>Apr</u> 99	Total
s of April 50, 1999	Goal		98 rea is prior t			99	99	99	
CHILE									
Sótero del Río, Puente Alto	37			34	4	3	5	4	50
Universidad Catolica, Santiago	9	7	3	3	1	5	1		15
JSA			-	-					
Univ Utah, Salt Lake City	6	5	2	2					10
Univ New Mexico, Albuquerque	10	5	2	3			1	1	10
Boston Medical Center	5	0	1	2 2	1		1	1	5
Baylor College of Medicine, Houston	12		1	2	1	1	1		4
Maricopa, Phoenix	8		-	3		-	1		4
Univ Iowa, Iowa City	4		3	-					3
Univ Michigan, Ann Arbor	8			3					3
Hutzel, Detroit	16			2				1	3
Oregon Health Sci Univ, Portland	6			2					2
Univ Mississippi, Jackson	9			1	1				2
Univ Maryland, Baltimore	4	1				1			2
Texas Tech Univ, Lubbock	6			1					1
Harbor, Baltimore	4			1					1
Centre(s) no longer recruiting									7
IMBABWE									
Harare Maternity	39		1	23	4	5			33
INLAND									
Central University, Helsinki	13	15	4	3		1			23
	15	15	4	5		1			
ROMANIA				2		1			
IOMC-Polizu, Bucharest	9			2	1	4	8	6	21
OLAND									
NRI of Mother & Child, Warsaw	6		4	2		1	1	1	9
Polish Mothers Memorial, Lodz	11			3		3			6
University of Gdansk	5	1	2	1		1			5
EGYPT									
Assiut University	12		4	8	2	2	1	1	18
UGOSLAVIA									
Novi Sad	15	5	10	1			1		17
		5	10	1					
WITZERLAND	7	1 2		4		1	1 1		11
Hôpitaux Universitaires, Geneva Regionalspital, Biel	7	3	4	4					11
	2		2	1					3
ORTUGAL			-						
Distrital, Faro	7			11		1			12
THE NETHERLANDS									
Atrium, Heerlen	5			8		2	2		12
MEXICO			-	-	-				
Dr M G Gonzalez, Mexico DF	12		3	5					8
			-			1			÷
SERMANY	A			=	1				-
Ludwig Maximilians, Munich	4 3	1		5	1				6
University, Bonn	3	1	<u> </u>						1
IEW ZEALAND									
Queen Mary Maternity, Dunedin	5			1					1
ENMARK									
No Longer Recruiting									1

April 30, 1999, centres awaiting first patient: Centre, *city*, COUNTRY, (annual goal) [month/year start-up package sent]

Charite, Virchow Klinikum, Berlin, GERMANY (9) [3/99]; Slaska Akademia Medyczna, Bytom, POLAND (4) [3/99]; Sunderland Royal, Sunderland, UK (10) [1/99]; Diana Princess of Wales, Grimsby, UK (6) [1/99]; Jefferson Medical College, Philadelphia, USA (6) [9/98]; Countess of Chester, Chester, UK (10) [7/98]; Hosp Parroquial de San Bernardo, Santiago, CHILE (9) [6/98]; Royal University, Saskatoon, CANADA (11) [4/98].