TERM BREECH TRIAL

Noticias News Nouvelles

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Total recruited in December: 74
Overall Total: 1055

If your recruitment is slow, or has slipped a bit in the past month, please make a redoubled commitment to the Term Breech Trial one of your New Year's resolutions.

A continued effort is required to keep our accrual on target and to complete the Trial on time. Together we can make it happen!

Mugs this month:

(for centres reaching or passing their annual goal)

Guelph General, *Guelph*, CANADA **(#3)**; **LC Lagomaggiore**, *Mendoza*, ARGENTINA **(#3); Assiut University**, *Assiut*, EGYPT; **Hospital das Clinicas da UFPE**, *Recife*, BRAZIL; **Civil Hospital**, *Karachi*, PAKISTAN.

Centres recruiting for the first time: **Royal Alexandra**, *Edmonton*, CANADA.

The Interim Analysis of the first 1000 patients…

Now that we have enrolled the 1000th patient, we are concentrating on getting everything ready for the analysis. To those of you who have been working hard to get your data booklets to us quickly: Thank you! Your support is much appreciated.

If you still have data outstanding, or overdue, now is the time to pull out all the stops - complete the booklets and send them in. The same thing applies to queries and corrections.

Remember that just one outstanding case can delay the whole process. We're counting on your help.

A reminder to everyone:

Please complete and return the non-randomised patient logs regularly. They will provide data that will assist us in looking at the generalisability of the Trial results. The logs can also be useful to you in documenting patients who were not approached or the reasons for patient refusals.

Two important points:

Baseline information must be completed in the *Entry* form before enrolling a patient in the Trial and before the randomisation call is made. It is very important that these data are collected and recorded before the allocation group is assigned. Doing this will also help you to confirm eligibility and will provide you with all the information you need for the call to the randomisation service.

Ensure that you are reporting parity and not gravidity. Trial participants are being randomised within parity groups (0 and ≥ 1), so the report of parity must be accurate. If there is any possibility that your centre may have reported gravidity for any patient, please contact us and we will work with you to set it right.
The following definitions may be helpful:

Gravidity: number of previous pregnancies

Parity: number of previous births ≥ 20 weeks

A teleconference was held recently among members of the Steering Committee and many of the Canadian Collaborators. Since the topics that we discussed may be of general interest, we include some notes from the teleconference here.

Raising uncertainty and disseminating information:
Among colleagues, the approach may need to be based on the customary local practice. In centres where vaginal delivery is usual, they may not want to "give up" patients to elective C/S, whereas in centres where C/S for breech is the norm, some may be hesitant to submit their patients to a trial of labour. Through presentations, rounds, and informal discussion, the concept of uncertainty needs to be raised: at this point the scientific evidence is not sufficient to indicate whether one form of management is better. An individual approach needs to be considered, with the centre investigator talking regularly to any reluctant colleagues. It may help to target the leader of those who are doing vaginal breech deliveries, since that individual's support may bring others along. For most women, their physician's opinion has great value, so it is important to encourage a comprehensive program of support for the trial, among both family doctors and obstetricians.

Some women, on hearing that vaginal delivery is a possibility, will choose this rather than the trial. It is important to develop a very balanced way of describing the 3 care options: participation in the trial, vaginal delivery, or C/S. Risks and benefits should be fairly presented for both forms of management, particularly since a woman may believe that C/S presents no risk at all to the baby. Women who want control over the decision making, can be reminded that participation in the trial is a choice; an appeal to altruism may also be successful.

Raising awareness and uncertainty among the public can be important in helping a potential participant to get similar information from multiple sources. Articles in the lay press, local television spots or interviews (eg with a former participant), public display of posters etc. are some of the methods that have been used.

It is also important that prenatal educators are well-informed; there are some who still present the information that a breech presentation means an automatic decision for C/S. An investigator might meet with a group of educators to present the trial, the patient video can be provided as an added teaching aid, or a coordinator might attend the classes at which this information will be provided.

Consultation and the buddy system:
Setting up a consultation mechanism for the trial may provide younger or less experienced physicians with the opportunity to learn vaginal breech delivery techniques. The senior colleague needs to suggest this, since it will require some commitment of his or her time and junior colleagues may be hesitant to express their concerns. If the senior colleague is the trial investigator, this will further underline his or her support for the trial. A potential participant may also be more willing to enter if she feels that she and her physician have this backup.

Fetal weight assessment:
Although ultrasound assessment is one way of estimating fetal weight, it is not necessarily the preferred method, although it may be especially useful if a large baby is suspected. If it is necessary to assuage concerns about recruiting big babies, the maximum weight cut-off can be set at a value that is within the local comfort range (eg 3500 gm). It may also be important to arrange a scheduled reassessment of eligibility for women recruited at 37 weeks, to allow for a planned C/S if it is required, rather than a "surprise" or emergency one.

Head entrapment:
The "stuck head" is a fear expressed by potential participants. They need to be reassured that it is very rare and that there is a method suggested for dealing with it (reprinted below from the November 1997 Newsletter). They may also need to be made aware that this type of risk is not necessarily restricted to vaginal breech delivery. Physicians who are concerned about this could be reminded that it is more often the result of "interference", as

The Term Breech Trial requires that a Caesarean section be undertaken if labour is prolonged or if the fetus is not able to deliver spontaneously to the umbilicus. If this approach is followed, fetopelvic disproportion and difficulty with the delivery of the aftercoming head, because of disproportion, should not occur unless the fetus has an abnormally large head. However, it may be possible for a fetal head to become deflexed during labour, particularly if there is some fetal hypoxia or asphyxia. If the head becomes deflexed during labour there may be difficulty with the delivery of the aftercoming head. Should this occur, we recommend the following manoeuvre: rotate the fetal head manually into the oblique diameter of the pelvis (to give yourself the most room), place the fingers of one hand on the maxilla of the fetus (inside the vagina) and the other hand suprapubically, and bimanually flex the fetal head. The fetal head should flex easily and drop into the pelvis and can then be delivered without further difficulty.

To avoid the development of deflexion of the fetal head during labour, we would ask that practitioners monitor the fetal heart rate (FHR) particularly closely towards the end of the first stage of labour and throughout the second stage. If the method of monitoring is intermittent auscultation, it is preferable to use Doppler ultrasound (either a hand-held Doppler or an electronic FHR monitor) to ensure fetal well-being. If there is evidence of FHR abnormalities suggesting fetal compromise, a Caesarean section should be undertaken rather than persisting with further attempts at vaginal delivery.


Our warmest wishes to you all as we enter 1999.

Recruitment

Recruiting centres as of December 31, 1998

(shaded area is prior to recruitment)

	Annual Goal	Jan-Dec 97	Jan-Jun 98	Jul-Sep 98	Oct 98	Nov 98	Dec 98		Total
CANADA	**159**	**63**	**51**	**11**	**7**	**2**	**6**		**140**
PAKISTAN	**35**	**13**	**54**	**15**	**9**	**22**	**8**		**121**
UK	**150**	**43**	**32**	**16**	**5**	**6**	**2**		**104**
ARGENTINA	**33**	**13**	**26**	**21**	**10**	**5**	**10**		**85**
AUSTRALIA	**51**	**14**	**36**	**12**	**5**	**3**	**1**		**71**
INDIA	**45**	**14**	**18**	**26**	**5**	**2**	**4**		**69**
SOUTH AFRICA	**41**	**12**	**28**	**18**	**2**	**3**			**63**
BRAZIL	**42**	**1**	**19**	**25**	**8**	**4**	**5**		**62**
ISRAEL	**96**	**15**	**21**	**12**	**4**	**3**	**6**		**61**
USA	**114**	**16**	**11**	**11**	**5**	**3**	**3**		**49**
CHILE	**46**	**7**	**3**	**18**	**5**	**4**	**10**		**47**
JORDAN	**42**	**1**	**10**	**12**	**8**	**7**	**7**		**45**
ZIMBABWE	**39**		**1**	**18**	**3**	**2**			**24**
FINLAND	**13**	**15**	**4**	**1**		**1**	**1**		**22**
YUGOSLAVIA	**15**	**5**	**10**				**1**		**16**
SWITZERLAND	**9**	**3**	**6**	**1**		**1**	**3**		**14**
POLAND	**22**	**1**	**6**	**5**	**1**				**13**
EGYPT	**12**		**4**	**3**	**3**		**2**		**12**
PORTUGAL	**7**			**3**	**3**	**3**	**2**		**11**
MEXICO	**12**		**3**	**5**					**8**
THE NETHERLANDS	**5**			**5**	**1**		**2**		**8**
GERMANY	**7**	**1**		**2**		**3**			**6**
ROMANIA	**9**					**1**	**1**		**2**
NEW ZEALAND	**5**					**1**			**1**
DENMARK No longer recruiting									**1**
Total	**1009**	**237**	**343**	**240**	**84**	**76**	**74**		**1055**

CANADA									
Riverside, Ottawa	6	19	10	3	3				**35**
Guelph General	4	8	1			1	2		**12**
St Joseph's, London	11	7	3						10
Sunnybrook & Women's College, Toronto	8	6	2	1					**9**
Misericordia, Edmonton	9		6	1			1		8
St Boniface, Winnipeg	10	4	3						7
Grey Nuns', Edmonton	9		6						6
Foothills, Calgary	12		2		1	1	2		6
BC Women's, Vancouver	19	1	4						5
Kingston General	6		2	3					5
St Joseph's, Hamilton	8		2		3				5
Scarborough Centenary	7	3	1						4
Regina General	9	1	3						4
Mississauga	8	1	2						3
Royal Victoria, Barrie	4	1	2						3
Ottawa General	7	1		1					2
York County, Newmarket	5			2					2
Montfort, Ottawa	6		1						1
Royal Alexandra, Edmonton	11						1		1
Centre(s) no longer recruiting									12

Recruiting centres as of December 31, 1998	Annual Goal	Jan-Dec 97	Jan-Jun 98	Jul-Sep 98	Oct 98	Nov 98	Dec 98		Total
		(shaded area is prior to recruitment)							
PAKISTAN									
Jinnah PMC, Karachi	14	6	46	15	9	14	4		**94**
Civil, Karachi	11					8	4		**12**
Aga Khan Univ, Karachi	6	7	2						**9**
Liaquat National, Karachi	4		6						**6**
UK									
Treliske, Truro	11	5	4	7	1	3	1		**21**
Bradford Royal Infirmary	11	7	5	2					**14**
Arrowe Park, Wirral	11	6	6	1	1				**14**
Liverpool Women's	14	7	3	1	1				12
Leeds General Infirmary	11	7	3			1	1		**12**
Peterborough Maternity Unit	9	3	2		1				6
Ormskirk General	3		2	3		1			**6**
Friarage, Northallerton	4	3	2						**5**
St John's, Chelmsford	10		3						3
Ipswich	10	2							2
Pilgrim, Boston	5		1	1					2
Royal United, Bath	9			1	1				2
Lewisham	7	1							1
St James's University, Leeds	12	1							1
Northern General, Sheffield	8		1						1
North Staffordshire, Stoke on Trent	15					1			1
Centre(s) no longer recruiting									1
ARGENTINA									
LC Lagomaggiore, Mendoza	19		18	18	8	4	10		**58**
Maternidad "Martin", Rosario	11	7	7	1	1				**16**
Ramos Mejia, Buenos Aires	3		1	2	1	1			**5**
Centre(s) no longer recruiting									6
AUSTRALIA									
Caroline Chisholm Centre, Liverpool	7		10	6	3	1			**20**
Mornington Peninsula, Frankston	5	9	3	2	1	1			**16**
Logan, Meadowbrook	8		10						**10**
St George, Sydney	7	2	4	2					**8**
King George V, Sydney	12	2	1	2	1	1	1		8
Gosford	7		3						3
Mona Vale	2		3						**3**
Women's & Children's, Adelaide	3	1	1						2
Centre(s) no longer recruiting									1
INDIA									
Nowrosjee Wadia, Mumbai	13	12	8	7	1	2	2		**32**
Christian Medical College, Vellore	14	2	10	10	3		1		**26**
LTMMC & LTMGH, Mumbai	18			9	1		1		11
SOUTH AFRICA									
Medunsa	25		23	17	2	2			**44**
Coronation, Johannesburg	16	12	5	1		1			**19**
BRAZIL									
Jundiaí, São Paulo	6		8	12	2	1			**23**
ISCMPA, Porto Alegre	13		1	9	5	1	2		**18**
Hosp das Clinicas da UFPE, Recife	10		7	2			2		**11**
Materno Infantil, Goiânia	13	1	3	2	1	2	1		10
ISRAEL									
Ma'ayney Hayeshua, Bene Beraq	10	8	7	1	1		1		**18**
Makassed Islamic, Jerusalem	5		9	3			1		**13**
Edith Wolfson, Holon	9		1	3	1	1	2		8
Meir, Kfar Saba	14	5				1			6
Poriya, Tiberias	5	2	2		1		1		**6**
Bnai-Zion, Haifa	10			4			1		5
Soroka, Beer Sheba	25		2	1					3
Chaim Sheba, Tel Hashomer	18				1	1			2

Recruiting centres as of December 31, 1998	Annual Goal	Jan-Dec 97	Jan-Jun 98	Jul-Sep 98	Oct 98	Nov 98	Dec 98		Total
		(shaded area is prior to recruitment)							
USA									
Univ Utah, Salt Lake City	6	5	2	2		1			**10**
Univ New Mexico, Albuquerque	10	6	1	1			1		9
St John's Mercy, St Louis	16	4	3						7
Univ Iowa, Iowa City	4		3						3
Univ Michigan, Ann Arbor	8			3					3
Baylor College of Medicine, Houston	12		1	2					3
Maricopa, Phoenix	8			1	1	1			3
Boston Medical Center	5		1		1		1		3
Oregon Health Sci Univ, Portland	6			1	1				2
Hutzel, Detroit	16					1	1		2
Univ Maryland, Baltimore	4	1							1
Texas Tech Univ, Lubbock	6			1					1
Harbor, Baltimore	4				1				1
Univ Mississippi, Jackson	9				1				1
CHILE									
Sótero del Río, Puente Alto	37			18	5	2	9		**34**
Universidad Catolica, Santiago	9	7	3			2	1		**13**
JORDAN									
Princess Badeea, Irbid	24	1	7	7	8	6	5		**34**
Islamic, Amman	18		3	5		1	2		11
ZIMBABWE									
Harare Maternity	39		1	18	3	2			24
FINLAND									
Central University, Helsinki	13	15	4	1		1	1		**22**
YUGOSLAVIA									
Novi Sad	15	5	10				1		**16**
SWITZERLAND									
Hôpitaux Universitaires, Geneva	7	3	4	1		1	2		**11**
Regionalspital, Biel	2		2				1		**3**
POLAND									
NRI of Mother & Child, Warsaw	6		4	1	1				**6**
University of Gdansk	5	1	2	1					4
Polish Mothers Memorial, Lodz	11			3					3
EGYPT									
Assiut University	12		4	3	3		2		**12**
PORTUGAL									
Distrital, Faro	7			3	3	3	2		**11**
MEXICO									
Dr M G Gonzalez, Mexico DF	12		3	5					8
THE NETHERLANDS									
Atrium, Heerlen	5			5	1		2		**8**
GERMANY									
Ludwig Maximilians, Munich	4			2		3			**5**
University, Bonn	3	1							1
ROMANIA									
IOMC-Polizu, Bucharest	9					1	1		2
NEW ZEALAND									
Queen Mary Maternity, Dunedin	5					1			1
DENMARK									
No Longer Recruiting									1

December 31, 1998, centres awaiting first patient: Centre, *city*, COUNTRY, (annual goal) [month/year start-up package sent]

Prof A Posadas, *Buenos Aires*, ARGENTINA (10) [11/98]; **Jefferson Medical College,** *Philadelphia*,USA (6) [9/98]; **CUSE (Site Fleurimont),** *Sherbrooke*,CANADA (8) [9/98]; **Countess of Chester,** *Chester*,UK (10) [7/98]; **Hosp Parroquial de San Bernardo,** *Santiago*, CHILE (9) [6/98]; **National Women's,** *Auckland*, NEW ZEALAND (31) [5/98]; **Brantford General,** *Brantford*, CANADA (4) [5/98]; **Royal University,** *Saskatoon*, CANADA (11) [4/98]; **Instituto Materno Infantil de Pernambuco (IMIP),** *Recife*, BRAZIL (15) [3/98]; **Oakville-Trafalgar Memorial,** *Oakville*, CANADA (5) [3/98]; **Coombe Women's,** *Dublin*, IRELAND (16) [2/98]; **Virchow Klinikum**, *Berlin*, GERMANY (9) [10/97]; **Mount Sinai**, *Toronto*, CANADA (12) [8/97]; **West Cumberland**, *Whitehaven*, UK (4) [3/97]; **North Bay General**, *North Bay*, CANADA (3) [2/97].