



BULLETIN

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OVERALL TOTAL: 186

TOTAL FOR THIS MONTH: 34

Welcome to EECV2!

We are pleased to announce that three more sites have now joined us! We now have 45 collaborating centres! A very warm welcome goes out to:



- Dr Jeffrey Pollard and Ms Cheryl Swaby at the CRHA, *Calgary, CANADA*
- Dr Mark H. Yudin and Ms Catherine Moravac at St Michael's Hospital, *Toronto, CANADA*
- Dr Miriam Muñoz at the University of Barcelona, *Barcelona, SPAIN*

We are pleased to have these new centres collaborating with us to help answer the very important question of best timing for ECV!

Recruitment Excellence!

This month we are recognizing centres with their **first** recruit - Congratulations to:

- Dr Marion Heres and Ms Monique Hoonings at Sint Lucas Andreas Ziekenhuis, *Amsterdam, THE NETHERLANDS*



Special recognition to centres who have met their Annual Recruitment Goal this month:

- Dr Jorge Carrillo at Padre Hurtado Hospital, *Santiago, CHILE*
- Dr David Gibson at the Toowoomba Base Hospital, *Toowoomba, AUSTRALIA*

Recruitment

(planned enrolment of 1460)

as of October 31, 2005

Annual Goal	Dec	Jan -	Jul	Aug	Sept	Oct	Grand Total
	2004	Jun 2005	2005	2005	2005	2005	

COUNTRY

COUNTRY	Annual Goal	Dec 2004	Jan - Jun 2005	Jul 2005	Aug 2005	Sept 2005	Oct 2005	Grand Total
AUSTRALIA	39		17	5	13	6	9	50
CHILE	43		10	5	7	4	14	40
THE NETHERLANDS	12		11		7	5	2	25
CANADA	36	1	11	1		3	1	17
ISRAEL	38		8	1	2	1	2	14
JORDAN	14		6	2	1	2	1	12
ARGENTINA	10		5	1	2		1	9
IRELAND	19					6	1	7
USA	10		1		1	2	1	5
GERMANY	9				1	1	2	4
EGYPT	20		1		2			3
Total	250	1	70	15	36	30	34	186

CENTRES BY COUNTRY

(Shaded area is prior to start-up)

AUSTRALIA

Centre	Annual Goal	Dec 2004	Jan - Jun 2005	Jul 2005	Aug 2005	Sept 2005	Oct 2005	Grand Total
Box Hill, Box Hill	5		4	3	5	2	6	20
Toowoomba Base Hospital, Toowoomba	3		10	1	2	1	1	15
St George, Sydney	6		1		4		1	6
Royal Prince Alfred, Sydney	9		2		2	1		5
Royal Women's, Carlton	11					2	1	3
Townsville Hospital, Townsville	5			1				1

CHILE

Centre	Annual Goal	Dec 2004	Jan - Jun 2005	Jul 2005	Aug 2005	Sept 2005	Oct 2005	Grand Total
Padre Hurtado, Santiago	17		3	4	5	3	7	22
Universidad Catolica, Santiago	7		4	1	2		3	10
Clinico san Borja, Santiago	19		3			1	4	8

THE NETHERLANDS

Centre	Annual Goal	Dec 2004	Jan - Jun 2005	Jul 2005	Aug 2005	Sept 2005	Oct 2005	Grand Total
Atrium Medical Centre, Heerlen	5		8		5	4		17
Academisch Ziekenhuis, Maastricht	3		3		2	1	1	7
Sint Lucas Andreas Ziekenhuis, Amsterdam	4						1	1

CANADA

Centre	Annual Goal	Dec 2004	Jan - Jun 2005	Jul 2005	Aug 2005	Sept 2005	Oct 2005	Grand Total
Children's and Women's Health Centre of BC, Vancouver	18	1	9	1			1	12
Sunnybrook & Women's College, Toronto	10		2			1		3
St Paul's, Vancouver	4					1		1
Lion's Gate, Vancouver	4					1		1

ISRAEL

Centre	Annual Goal	Dec 2004	Jan - Jun 2005	Jul 2005	Aug 2005	Sept 2005	Oct 2005	Grand Total
Edith Wolfson, Holon	9		4			1	1	6
Meir Hospital, Kfar Saba	14		3	1			1	5
Ma'ayney-Hayeshua, Bnai Brak	15		1		2			3

Annual Goal	Dec 2004	Jan - Jun 2005	Jul 2005	Aug 2005	Sept 2005	Oct 2005	Grand Total
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JORDAN

Islamic, Amman	14		6	2	1	2	1	12
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ARGENTINA

Posadas, Buenos Aires	10		5	1	2		1	9
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IRELAND

Coombe Women's, Dublin	19					6	1	7
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USA

University of South Carolina, Columbia	6					2	1	3
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University of Iowa, Iowa City	4		1		1			2
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GERMANY

Charite Universitatsklinikum, Berlin	9				1	1	2	4
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EGYPT

Assiut University Hospital, Assiut	20		1		2			3
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Centres awaiting first patient: [COUNTRY: Hospital, City (annual goal)] [month/year start-up package sent]

AUSTRALIA: West Gippsland Healthcare Group, *Warragul* (2) [03/05] **USA:** Maricopa, *Phoenix* (10) [04/05]; **ISRAEL:** Soroka Medical Center, *Beer Sheva*, (30) [06/05]; **POLAND:** Polish Mother's Memorial, *Lodz* (9) [03/05], Medical University of Gdansk, *Gdansk* (5) [09/05]; **BRAZIL:** University of Campinas, *Campinas* (8) [04/05]; **HUNGARY:** University of Debrecen, *Debrecen* (7) [04/05]; **PORTUGAL:** Distrital de Faro, *Faro* (7) [04/05]; **ARGENTINA:** Hospital Ramos Mejia, *Buenos Aires* (6) [05/05], Hospital Avellaneda, *Tucuman* (10) [08/05]; **CANADA:** Regina Health Region, *Regina* (8) [06/05], Royal Alexandra Hospital, *Edmonton* (10) [06/05], Ottawa Hospital – General Campus, *Ottawa* (10) [08/05], Royal Columbian, *New Westminster* (7) [08/05], North Bay General, *North Bay* (2) [08/05], Mount Sinai, *Toronto* (16) [09/05], St Michael's Hospital, *Toronto* (7) [10/05], CRHA, *Calgary* (25) [10/05]; **SPAIN:** University of Barcelona, *Barcelona* (10) [10/05]

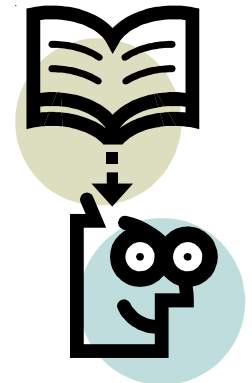
Intention to Treat Analysis – What does it mean?

Close, N. “Unlocking the Mysteries Behind Medical Statistics” SCT Pre-Conference Workshop. Portland, Oregon. May 22, 2005

“Intention to treat” (ITT) is a strategy for the analysis of randomised control trials that compares participants in the groups to which they were originally randomly assigned. Regardless of protocol violations, participant compliance or withdrawal, analysis is performed on all participants randomised.

The reason for using random assignment to treatment groups is to ensure that any known, or unknown variables that might be associated with the outcome are equally distributed between groups. Using an ITT approach ensures that treatment groups remain similar apart from random variation and avoids systematic variation or bias. This benefit of randomisation will be lost if analysis is not performed on the groups as determined by the randomisation process.

ITT generally gives a conservative estimate of the treatment effect compared with what would be expected if there was full compliance. By accepting that protocol deviations and non-compliance will occur in normal clinical practice, ITT essentially tests a treatment strategy and avoids over optimistic estimates of the efficacy of the intervention, thus increasing the generalisability of the findings to clinical practice.



Effectively Explaining Randomisation

It can be difficult to explain the concept of randomisation. However, it is very important that all participants approached about the trial understand and feel comfortable with this concept.



In the EECV2 Trial, randomisation means that women have a 50% chance of being assigned to having ECV done early (between 34 weeks 0 days and 35 weeks 6 days) and a 50% chance of having ECV done at the usual time (at or after 37 weeks 0 days).

In order for a woman to be randomised into the trial she should be comfortable with having the procedure done within either time frame and she must be eligible to receive either treatment. If she is beyond 35 weeks 6 days, for example, she would not be eligible to have an Early ECV and therefore could not be randomised into the study.

Resident/Student Involvement

A suggestion has come from our steering committee members regarding the involvement of students in the trial. There are many creative ways to involve learners in research and we encourage centres to involve students in various aspects of running the EECV2 Trial. We would love to acknowledge any students who have made a contribution to the trial at your site, and to share ideas about how this has worked. Please let us know how students are assisting your centre.

Quote of the Month

The value of achievement lies in the achieving.

~Albert Einstein

European Centres ... See you soon!



The last details are being finalised for the joint Twin Birth Study and EECV2 Trial meeting in London, England November 10th to 12th, 2005. We look forward to seeing our European Collaborators soon!

Don't forget to make arrangements for vacation time!



As the holiday season approaches be sure to make arrangements to cover for any of your EECV2 team who may be taking time off. Now is the time to discuss with the coordinator and other practitioners involved in the EECV2 Trial what should be done with women wanting to join the trial and undergo ECV while team members are away on holiday.