

SafeBoosC News

Newsletter,
Nov. 2012

Dear SafeBoosC participant,

To stay informed about recent movements within the SafeBoosC trial, please refer to this monthly newsletter

Burning Issues:

A new version of the off-line eCRF has been uploaded, please print and keep this in case you should not be able to access OpenClinica (OC)

Also, do not forget that screening failures should be entered into OC

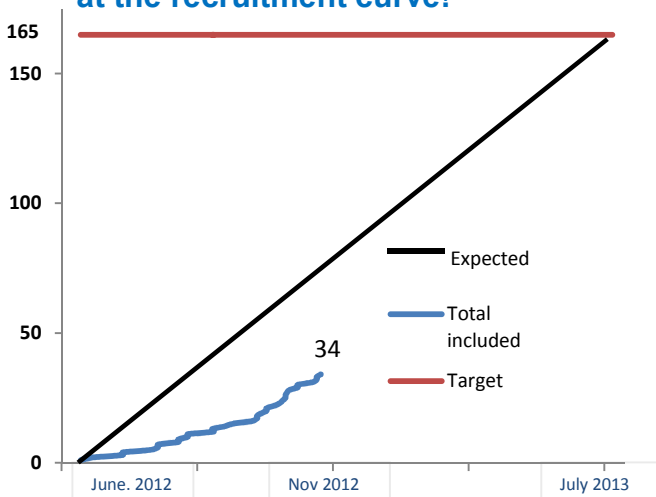
Inclusion Criteria:

Two siblings now count as two inclusions. One sibling may be included if locally ethically permissible.

Recruitment:

Eight sites have obtained full approval for the SafeBoosC trial. Seven are now enrolling. Utrecht has now obtained full approval and will have their initiation visit primo January 2013. Italy has recruited their first patient. Congratulations !

'Hurrah - now we may catch up. Look at the recruitment curve!'



Site	Recruiting	Screened	Included	hereof Twin-Pairs	Targeted
Graz	+	9	4	1	6
Leuven	-	0	0	0	6
Zurich	-	0	0	0	6
Tübingen	-	0	0	0	6
Copenhagen	+	37	15	4	28
Madrid	+	19	9	1	35
Lyon	+	5	5	1	20
Cork	+	2	0	0	25
Milan	+	1	1	0	6
Utrecht	-	0	0	0	15
Uppsala	-	0	0	0	6
Cambridge	+	0	0	0	6
Total		73	34	7	165

Consortium Agreement:

Axel Franz will be the PI for Tübingen. He will replace Claudia Roll who was not able to participate since the German Medicines Device Agency required 2 years of experience with device trials to be approved as a national PI.

SOPs/eCRF:

Are currently being revised, latest version can always be found at the website

Clinical Investigational Plan (CIP):

Most countries have now obtained full approval for trial initiation so shortly there will be an amendment: CIP v.4.0

Oxyprems: Those who are interested in testing these please contact Martin for organising this.

Up-scaling of recruitment target

As the consequence of two siblings being included a statistical analysis using multiple clusters will be used and there is a 'loss of degrees of freedom'. We have therefore up-scaled the targeted recruitment no. from 150 to 165 children – distributed among the sites by eyeballing. Siblings are always randomised to the same intervention group.

White layer on INVOS sensor

The reference data that defines the target range 55-85% was obtained using sensors without removing the white protecting layer. This layer reflects about 10% of the light, and the predictable result is that the field of measurement is slightly more superficial compared to the field with this layer is removed. As we use an adult sensors, this is unproblematic, but cannot be generally recommended as it is in contrast to the investigators brochure that has been approved by the device agencies in the relevant countries.

Reimbursement:

Two siblings (recruited as a pair) will be reimbursed with 150% which equals 30.000 DKK. Singletons (or one sibling of a set of multiples) will still be reimbursed by 20.000 DKK

Invoices for tasks completed within a financial year must be received by RH-NEO not later than December 20.

By mid. February we also need your Yearly Financial Report. This should include a statement of the actual co-financing of the project. You only need to state the amount and that this is "self-finance".

No further documentation is needed.

Gorm's reflection on the value of cerebral oximetry:

I was caring for a couple of twins randomised to the open group. One of them had cStO₂ of 75-80%, but the other just 55%. Both were very small - less than 500 g, but doing clinically well on nCPAP with normal blood gases, good blood pressures, and good haemoglobin and capillary refill. Both had very small ductuses. I did not do anything for the low cStO₂, several times during the night the oximeter alarm went off, and I typed in 'no action'. The next day I realised that I should probably have given her dobutamine. Low cardiac output with no real clinical signs is a well-known condition, and dobutamine could have helped. It could also have increased the likelihood that the SafeBoosC phase-II trial comes out with a positive result. CONCLUSION: Push yourself and your colleagues to think about what cerebral oximetry can add to what we know already!

/gorm

Calendar

SafeBoosC Annual F2F Meeting
Dragør, Denmark : March 14-15,
2013. Mark your calendar or even
better respond to Berit that you will
join☺

Best wishes,
Gorm & Berit