

SafeBoosC News

Dear All,

By now all sites should have amended the CIP v.4.0. Latest version of the CIP can always be downloaded from SafeBoosC.eu

I think it is fair to say that recruitment is catching up. As the last sites join we may finish this year.

New publications:

The phase-II trial protocol article is published by the journal ‘Trials’ (IF 2.5) with the following citation:

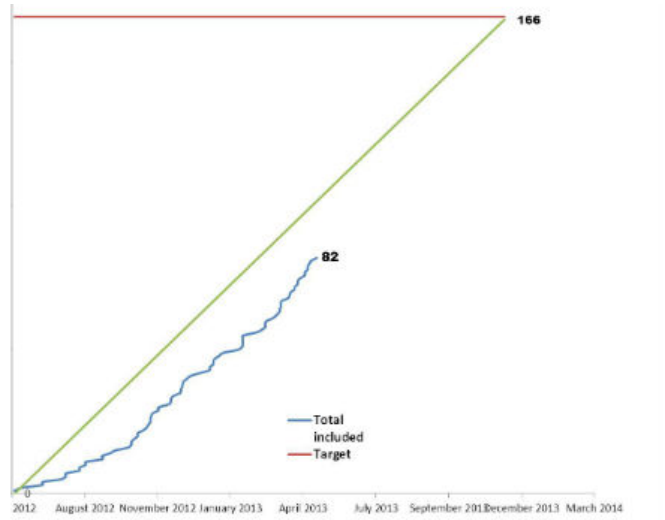
Trials.2013, 14:120.
DOI: 10.1186/1468-6708-14-120

URL:
<http://www.trialsjournal.com/content/14/1/120>

The treatment guideline article is in press in ‘Neonatology’

Data Management:

Don’t forget to fill in Compliance Form (72H) Previously named “Follow up” at 3 months has been renamed to “Follow up Term Date” When uploading your data via the FTP server please make sure to name the folders as requested, this will save us a lot of time when checking the data.



Study Site

Site	Screened	Included	Hereof twin pairs	Targeted
Graz	20	5	1	6
Leuven	0	0	0	6
Zurich	0	0	0	6
Tübingen	0	0	0	6
Copenhagen	49	22	5	29
Madrid	36	21	2	35
Lyon	21	16	1	20
Cork	11	6	3	25
Milan	5	4	0	6
Utrecht	5	2	0	15
Uppsala	0	0	0	6
Cambridge	9	6	0	6
Total	156	82	12	166

Recruitment per 8-may-2013

Data uploaded

Study Site	randomisations	Upload Oneweek		Upload term	
		NIRS	EEG	CUS	MRI
Graz	5	5 (0)	5(0)	3(-2)	0 (-5)
Leuven	0	-	-	-	-
Zurich	0	-	-	-	-
Tübingen	0	-	-	-	-
Copenhagen	22	22(0)	21(-1)	18(-4)	5(-17)
Madrid	21	20(-1)	11(-3)	10(-11)	7(-14)
Lyon	16	16(0)*	0(-16)**	0(-16)**	0(-16)
Cork	6	4(-2)	4(-2)	0(-6)	0(-6)
Milan	4	3(-1)	3(-1)	2(-2)	2(-2)
Utrecht	2	2(0)	2(0)	0(-2)	0(-2)
Uppsala	0	-	-	-	-
Cambridge	6	5(-1)	6(0)	2**	0(-6)
	82				

Status as of May 10th

The (-)number is the difference between the number of children included and the number of folders uploaded. If the child has not yet reached term, has died (before any data was collected), has had consent withdrawn or data is missing for other reasons you need to do nothing. **If you have forgotten to upload, please do so.**

** Some of the files have been handed in on paper or DVD – but please try to upload as much as possible – It will make the data-analysis much easier. Please upload in the folders in as described in the SOP “Data transfer to Copenhagen Trial Unit”

Link:

http://www.rigshospitalet.dk/NR/ronlyres/CBB5DACF-6702-4255-AB09-FC8C6BCF17A2/0/SOP_ftp_120921.pdf

Best wishes,

Gorm