Good Clinical Practice (GCP) in SafeBoosC III

“The trial will be conducted in compliance with the guidelines of the Declaration of Helsinki in its latest form and the International Conference on Harmonisation Good Clinical Practice guidelines (International Conference on Harmonization GCP) …”

How will the SafeBoosC III trial be monitored?

Pragmatic, no extras

Internal monitoring - *Copenhagen Trial Unit*

- Check of trial recruitment
- Quality, completeness and timeliness of data entry

Statistics of internal monitoring will be published on safeboosc.eu

In case of problems, national coordinators will be contacted

External monitoring

Local GCP person

- A person with GCP training, not involved in the trial

Work according to monitoring plan

- Initiation visit
- Monitoring visits

Initiation visit

Must take place before inclusion of patients

- Trial Master File completeness
- Organisation plan for inclusion 24/7
- Submit report to Copenhagen

On-site monitoring

- 1st visit: after first patient
- 2nd-6th visit: approx every 5th patient

Pragmatic monitoring

- Existence of clinical file and signed consent form
- Source data verification

Monitoring report must be send to Copenhagen

Source data verification

eCRF against clinical files

- Group allocation
- Whether the participant is dead or alive at 36+0 weeks postmenstrual age
- IVH grade 3 or 4, cPVL, cerebellar haemorrhage, ventricular dilatation or cerebral atrophy at any time before 36+0 weeks postmenstrual age
- Performance of early (3-8 days from birth) and/or late (>35 days from birth) cranial ultrasound

Plans

1. Meeting with GCP experts mid-November
2. Uploading final GCP monitoring plan including report templates to www.safeboosc.eu

Funding? Awating Medtronics