

ALBINO - Checklist participating hospitals



Site-ID - City

Principle investigator of this site:

Investigator hospital - name:

Investigator hospital - Address:

Investigator Email - Address:

Investigator hospital - phone number:

Contact person in your hospital / ward

Contact person **aEEG recording**:

name:

email:

phone

(only if different from above): address

Contact person **mchEEG recordings**:

name:

email:

phone

(only if different from above): address

Contact person **(Neuro-)Radiology**
(i.e., for MRI)

name:

email:

phone

(only if different from above): address

Contact **research nurse** who will be responsible
for ALBINO:

name:

email:

phone

(only if different from above): address

Address for shipment of study medication
including **responsible** contact

name of

contact:

email:

phone

address

Contact person responsible for **24 months neurological assessment:**

name: _____
email: _____
phone _____
address _____

Contact person responsible for **24 months Bayley III:**

name: _____
email: _____
phone _____
address _____

If applicable:

- Contact of **additional neonatologist:**

name: _____
email: _____
phone _____
(only if different from above): address _____

- Contact **person Obstetrics:**

name: _____
email: _____
phone _____
(only if different from above): address _____

- Contact **person Pharmacy:**

name: _____
email: _____
phone _____
(only if different from above): address _____

- Contact **person Laboratory:**

name: _____
email: _____
phone _____
(only if different from above): address _____

Contact - #

Chairman of the responsible Ethics Committee:

name: _____
email: _____
phone: _____

-

name: _____
address: _____

Information required for EC and RA submissions, Feasibility of ALBINO study, Expected Recruitment

Recruitment

Expected recruitment number of neonates undergoing hypothermia: ⇨ number: _____

Expected recruitment number of neonates meeting inclusion criteria but not undergoing hypothermia: ⇨ number: _____

Required documents and qualifications

Good clinical practice (GCP) certificate for local principal investigator, deputy investigator(s), study nurse(s)

→ **please send by email!**

CV investigator(s)/research nurse

→ **please send by email!**

Financial Disclosure investigator(s)/research nurse(s) (see template provided)

→ **please send by email!**

Medication

Feasibility to store medication in operating room/delivery room/resuscitation suite. Yes No

Feasibility to obtain a secure intravenous access within 30 minutes. Yes No

Feasibility to prepare and administer intravenous medication within 30 minutes. Yes No

Standard of care

→ **please tick "Yes" if this is possible in your hospital**

In Infants meeting hypothermia criteria Yes infants will be transferred to other hospital to start therapeutic hypothermia

If yes: which is your referral hospital?

Yes _____
perform hypothermia in own hospital

Yes Other: _____

In infants with fast recovery and no need for hypothermia Yes Cranial ultrasound feasible (desirable)

Yes aEEG feasible (desirable)

Yes Multichannel EEG feasible (desirable)

Yes MRI feasible (desirable)

Yes NIRS feasible (voluntary)

Laboratory

→ please tick "Yes" if this is possible in your hospital

- Possibility to determine blood gases within 30 minutes after birth Yes
- Centrifuge in walking distance which are suitable for EDTA tubes and for Eppendorf tubes Yes
- Possibility to centrifuge blood samples within 10 minutes Yes
- Freezer (cooling from -70C to -80C) in walking distance to store blood/urine samples within 3 days Yes
- Freezer (cooling from -20C to -30C) to store blood/urine for up to 3 days if not directly stored in -80°C Yes

2-Year-Follow-up

→ please tick "Yes" if this is possible in your hospital

- Follow-up at 2 years of age: Bayley III, gross motor function classification system (GMFCS) according to surveillance of cerebral palsy in Europe (SCPE) **at your hospital?** Yes
- Follow-up at 2 years of age: Bayley III, gross motor function classification system (GMFCS) according to surveillance of cerebral palsy in Europe (SCPE) **at another institution?** Yes

If yes:

Name of the institution: _____

Name of the contact person on-site: _____

email: _____

phone : _____

full adress: _____

Questions referring to aEEG or EEG

Local routines

- Are you able to do aEEG monitoring on infants in ALBINO trial? Yes No
- Are you routinely monitoring infants who undergo hypothermia treatment with aEEG? Yes No

If Yes:

Please describe your routine aEEG Monitoring **in infants undergoing hypothermia:**

Start aEEG: _____

Duration aEEG: _____

Add. description: _____

Please describe your routine aEEG Monitoring in infants with asphyxia, **who do not qualify for hypothermia:**

Start aEEG: _____

Duration aEEG: _____

Add. description: _____

Device Manufacturer

Which **aEEG device** are you currently using?

- OBM (Olympic Brainz Monitor)
- BrainZ Monitor
- Olympic 6000
- Nicolet (NicOne)
- Unique CFM
- Other

if Other: _____

Which **multichannel EEG (mchEEG) device** are you currently using?

- Nicolet (NicOne)
- Micromed
- Nihon Kohden
- Other

if Other: _____

EEG storage

How do you currently store aEEG recordings?

- Print-out
- Discs
- USB
- server

How do you currently store Multichannel EEG recordings?

- Discs
- USB
- server

Near future plans for aEEG/mchEEG

We trust that you are aware of the changing situations:

First, that Olympic and BrainZ monitoris are no longer serviced.

Second, that ALBINO has been offered a possibility to obtain very high quality systems that are able to do **both aEEG and multichannel EEG**. In addition, these systems would also have an automatic data transfer to the study server if you want to use that option.

These systems would be either with a lease agreement or direct purchase, both options much cheaper than the other available options.

More information: <http://www2.lifelinesieeg.com/lifelines-r40.html>

Are you planning to renew your **aEEG or EEG device** within the next three years?

- Yes No

Would you be interested in exploring the above option?

- Yes No

Questions referring to MRI and CUS

MRI (Magnetic Resonance Imaging)

In infants who **undergo hypothermia** is MRI part of standard care / standard assessment in your hospital? Yes No

If yes:

Timing of MRI: (from...to) _____ days after birth

If no (i.e. if MRI is not standard assessment)

would it still be feasible to do MRI in ALBINO infants within 2-10 (preferably 4-6) day of life? Yes No

In infants meeting ALBINO inclusion criteria but **not qualify for hypothermia** is MRI part of standard care / standard assessment in your hospital? Yes No

If yes:

Timing of MRI: (from...to) _____ days after birth

If no (i.e. if MRI is not standard assessment)

would it still be feasible to do MRI in ALBINO infants within 2-10 (preferably 4-6) day of life? Yes No

MRI brand (e.g. Siemens/Phillips...): _____

MRI Tesla (3T/1,5T/...): _____

Willing to adjust protocol/sequences? (orientation, slice thickness, gap etc.) Yes No

3D-T1/T2/DWI available? (required) Yes No

Option to measure ADC MAP? Yes No

Spectrometry (proton-MRS) available? Yes No

DTI available? Yes No

ASL available? Yes No

PCA available? Yes No

SWI available? Yes No

Other ongoing research projects with MRI in this population? Yes No

If yes please give further details: _____

CUS (Cranial Ultra Sound)

Possible to perform cranial ultrasound including doppler? Yes No Only cranial ultrasound without doppler

Possible to measure resistance index in intracranial internal carotid artery according to Pourlemot? Yes No Yes but not acc. to Pourlemot

Possible to save ultrasound images under study number? Yes No

Comments:

(City, date)

(Signature Principle Investigator)