

Minutes from steering committee meeting 18-nov 2019

Attending: Eugene Dempsey, Gunnar Nauelaers, Monica Fumagalli, Adelina Pellicer, Cornelia Hagmann, Hans Fuchs, Jonathan Mintzer, Jakub Tkaczyk, Ebru Ergenekon, Gabriel Patras, Gorm Greisen, Mathias Lühr Hansen

Apologies: Saudamini Nesargi, Gerhard Pichler, Ana Vilan, Siv Fredly, Simon Hyttel-Sørensen

Referent: Mathias Lühr Hansen

Status on trial preparations and randomisation in each country, national coordinators

Spain – Adelina Pellicer

Six hospitals have started enrolling babies, and eight more are preparing. Six of the eight hospitals preparing, have obtained ethics approval. There is a contractual issue in Spain, due to the grant which Adelina obtained earlier this year. In order for Adelina to distribute this money to Spanish hospitals, an agreement must be signed between Adelina as local sponsor, and Spanish hospitals - and the final set-up of contracts has not yet been decided

Switzerland – Cornelia Hagmann

Four hospitals will participate, and three of these are expected to start enrolling babies in the beginning of December - Zürich is already opened for randomisation. The fourth hospital still needs ethics approval.

Turkey – Ebru Ergenekon

Five hospitals will participate, and four of them are ready to enrol babies. As soon as the GCP monitor person has sent the GCP initiation visit reports for these four sites to Mathias, he will open for randomisation. The fifth hospital is expected to start within the next months as well.

Belgium – Gunnar Nauelaers

Six hospitals will participate in the trial. The main issue is still agreeing on a contractual set-up, since Gunnar also has achieved a grant which must be distributed between Belgian sites. However, the legal advisors in Belgium have been working hard to solve this problem, and Gunnar expects that it will be solved within the next two weeks. They expect to start enrolling babies in the beginning of 2020.

Germany – Hans Fuchs

Hans Fuchs is searching for additional German Hospitals to participate, but it has proven difficult without any funding. Datteln is still interested, Freiburg have submitted ethics application and the collaboration agreement is with the legal department. Freiburg expect to start enrolling babies in the beginning of 2020.

Ireland – Gene Dempsey

Three Irish hospitals will participate, a fourth is interested. Two of the Irish hospitals have ethics approval. The biggest issue in Ireland is to agree with Copenhagen on a contract, covering all Irish hospitals, since Gene in Cork will be national coordinator and local sponsor. However, Cork expects to start enrolling babies in the beginning of 2020.

Greece

Four hospitals will participate from Greece, one has already started to enrol babies. Two of the remaining three hospitals have ethics approval and have received Oxyprem devices. The last hospital is dealing with the tax office in order to get the Oxyprem devices into Greece. Gabriel expects that three of the four hospitals will enrol babies within the next two weeks.

Italy

Six hospitals will participate and one, the national coordinating centre in Milano, have started enrolling babies. The remaining five hospitals have problems getting ethics approval, since the ethics committees in Italy require patient insurance. However, Milano did not need insurance, so they have forwarded their ethics approval to the remaining five hospitals – hopefully this will help the remaining five hospitals getting around the need for insurance. Monica expects that an additional two hospitals will be able to start enrolling babies in a few months.

Czech Republic

Two hospitals will participate, one of them have already started enrolling babies. The last hospital expects to start randomising within the next two months but need to deal with some internal organisational changes before they can proceed.

US

Twelve hospitals are preparing to participate. Ten of them is involved in a funding application and will know the answer to this before the end of 2019. Six hospitals are active in ethics application process and one have gotten the approval. Main concern in the US is GCP, since their system differs from the European, and in many hospitals money for GCP is necessary - so the number of hospitals that will end up enrolling babies, depends on the present funding application.

News on Copenhagen funding

As mentioned in the newsletter, we were granted 1,000,000 dkk (150,000 Euro) in October. This money will cover the next three investigator meetings, as well as the first year of Copenhagen Trial Units work with running of the trial.

Collaborative investigator certificate

It was decided that a collaborative investigator certificate will be available to colleagues who have supported the principal investigator substantially with the conduct of the trial. If a principal investigator believes that a colleague should receive such a certificate, the principal investigator must send an e-mail to Mathias, stating the explicit tasks which the colleague has done within the hospital. This will be stated on the certificate, which will be signed by Gorm and sent to the principal investigator.

Approval of central monitoring plan

The central monitoring plan was approved after discussing the principle of transparency, which in this case means 'naming and shaming'. A mechanism to get missing data that is not possible to find, out of the calculated percentages will be available.

Sharing individual staff training results with principal investigators

It was decided that principal investigators will not be given information on individual staff members training activity.

Overcoming barrier regards to distribution of national grant money

This is an issue in multiple countries, including Spain, Turkey, Belgium, Ireland and Switzerland. Gorm proposes that Copenhagen should not be involved in such local affairs and suggest that contracts between

local grant holder and hospitals should be separate from the collaboration agreement between Copenhagen and participating hospitals. However, since regulations differ between countries, it is difficult to find a universal solution to this problem. The involved national coordinators will talk to their legal department about this matter, which hopefully will push the process forward and avoid any tri- or fourth-part-contracts.

Any other business.

Next SG-meeting will be before the PI-meeting in Copenhagen 23-24 Jan 2010 to finalise the agenda.