
Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Øyvind Straume	55978497	31.01.2017	2016/1620/REK vest
			Deres dato:	Deres referanse:
			04.01.2017	0000

Vår referanse må oppgis ved alle henvendelser

Tor Strand
Forskningsavdelingen

2016/1620 Effekten av vitamin B12-tilskudd hos Nepalske gravide på barnas vekst og utvikling

With reference to your appeal regarding the abovementioned project.

Institution responsible for the research: University in Bergen
Project manager: Tor Strand

Background

The project was reviewed by REC Western Norway in the meeting 27.10. REC Western Norway decided we need more information about:

1. The need for yet another study on vitamin B12.
2. Is it ethically acceptable to conduct a placebo controlled study, taken into consideration the scientific knowledge we already have on vitamin B12 and the fact that we must assume that many in the study population lack vitamin B12? Why not find a study design where all participants have vitamin B12?

REC Western Norway has also received an assessment from an external expert on these questions. The project manager has been asked to address the remarks in this report.

New assessment 24.11.2016

The Committee decided to reject the application based on the following points:

1. The problematic placebo arm.
2. Revealing deficiencies in the pregnant women and not treating them.
3. Current evidence.
4. Inconsistencies between the application and the response

The project manager appealed the decision and the appeal was assessed in the meeting 12.01.2017.

New factors in the appeal

The project manager again points to that there is insufficient current evidence and that the study is deemed necessary. There is attached a recommendation about supplementation for pregnant women from the WHO, where vitamin B12 is not included in the recommendation. The project manager points out that measurements taken at baseline will be analyzed in Norway, and will not be available on the premises until after a longer period.

Furthermore the local approval by the Ethics Committee in Nepal has been obtained.

Finally based on discussion raised by the ethics committee the research group suggests some changes in the project:

- There will be an early measurement of neuronal development at interim analysis at 100 patients enrolled

- Women planning to take B12 supplement will be excluded
- If the authorities change their recommendations on intake, the treatment will be given all.
- Where the study doctor finds it necessary to treat the woman with vitamin B12 or vitamin B12 containing supplements, the women will be excluded from the study and given treatment.

The Committee Chairman also chose to retrieve a second independent expert opinion, that was presented for the Committee.

New assessment 12.01.2017

Based on the changes and clarifications that have been made, the Committee chooses to approve the project.

The Committee considers it crucial that women who are considered to need treatment with B12 by the study doctor will receive this, and get excluded from the study.

The Committee emphasizes that all women participating will benefit from participation and that the safety monitoring presented is detailed and thorough. The Committee also emphasizes that WHO's recommendation does not include B12 and that there may be sufficient doubt about current evidence so that a placebo controlled trial can be ethically justified.

Vedtak

REC Western Norway accepts the appeal and approves the project.

Sincerely,

Marit Grønning
Prof. dr.med
Chairman

Øyvind Straume
Committee Secretary

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