Rapport og sluttmelding Skjema for løpende rapport eller sluttmelding til de regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK)

2015/597-16
Dokument-id: 1179254 Dokument mottatt 22.03.2019

Vankomycin, tarmbakterier og koagulasjon (2015/597)

1. Generelle opplysninger

a. Prosjektleder

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b. Prosjekt

Hvilket prosjekt gjelder sluttmeldingen/rapporten?	Vankomycin, tarmbakterier og koagulasjon (2015/597)

EudraCT-nummer 2015-001262-25

2. Sluttmelding/rapport og etisk vurdering

Sluttmelding

Kortfattet, allment forståelig framstilling av prosjektets konklusjoner. Dette gjelder både positive og negative funn.

This randomized controlled trial in healthyvolunteers supports the hypothesis that a Vancomycin-induced decreased gutmicrobiome diversity and increased gram negative composition results inincreased systemic inflammation, measured by hs-CRP, and FVIII:C. Futurestudies are warranted to investigate the relationship between the gutmicrobiome, inflammation and coagulation in subjects with a higher rate ofbacterial translocation.

Kortfattet redegjørelse for gjennomføringen av prosjektet i forhold til opprinnelig søknad og plan for gjennomføring.

The gut microbiome might be a source of systemic inflammation and activation of coagulation by translocation of lipopolysaccharides from gram negative bacteria to the systemic circulation. The primary objective of the study was to investigate whether a Vancomycin-induced shift of the gut microbiome in a gram negative direction influences systemic inflammation and plasma factor (F) VIII procoagulant activity (FVIII:C).

The study was conducted from Sept 15, 2016 until June 1, 2017 as a Randomized, single (investigator) blinded, controlled trial. The setting was at a Single-center trial in Norway. Fifty healthy volunteers were screened and randomized, and 43 participants aged 19-37 years completed the trial.

Feces and blood were sampled at baseline, the day after the intervention stopped, and three weeks later. Gut microbiome composition was assessed by a phylogenetic assay. Cytokines were measured using multiplex technology, complement activation was measured using ELISA, FVIII:C was measured using an APTT-based assay, and high-sensitivity (hs)CRP was measured by an immunoturbidimetric assay.

There were 21 subjects randomized to Vancomycin intervention and 22 subjects served as controls. Vancomycin intake reduced gut microbiome diversity and increased the abundance of gram negative bacteria. FVIII:C and hs-CRP increased significantly in the intervention group compared to the control group. The cytokines and complement activation markers remained similar in the two groups.

Potential effects of intervention on some cytokines in the range below the lower detection limits could not be detected. The Post-hoc calculation of study power was 70% for the main outcome.

Lenke til eventuell publikasjon	A manuscript is written and will soon be submitted for publication.

3. Vedlegg

#	Type	Filnavn	Lagt inn dato
1.	Sluttmelding / publikasjon	REK 2015-597 Vankomycin	22.03.19

	tarmbakterier og koagulasjon (002).docx

4. Ansvarserklæring

Jeg erklærer at prosjektet vil bli gjennomført
I henhold til gjeldende lover, forskrifter og retningslinjer
I samsvar med opplysninger gitt i denne søknaden
I samsvar med eventuelle vilkår for godkjenning gitt av REK