A phase I, randomised single center, open-label parallel group trial to compare the pharmacokinetics of NOMAC between healthy female adolescents (aged 14-17 years) and healthy female adults (aged 18-50 years) after single dose administration of NOMAC-E2 tablets

REC reference
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Title
A phase I, randomised single center, open-label parallel group trial to compare the pharmacokinetics of NOMAC between healthy female adolescents (aged 14-17 years) and healthy female adults (aged 18-50 years) after single dose administration of NOMAC-E2 tablets
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Contact name
Dr Jorg Taubel
Contact email
j.taubel@richmondpharmacology.com
Research summary
This study is being carried out to compare the blood levels of NOMAC-E2 in female adolescents when compared with female adults. In total 30 subjects (15 subjects, aged 14-17 subjects, aged 18-50 years) will receive one single oral dose (1 tablet) of NOMAC-E2. If the blood levels are the same in both populations, its is assumed that the efficacy will be the same. This in turn, will avoid having to do an efficacy study in the adolescent population.

NOMAC-E2 is a new contraceptive pill which is being developed with the anticipation that it will be effective in preventing pregnancies and have fewer side effects than currently available pills, as it contains the natural estradiol (E2). It is a combination pill, and both components of the pill are already on the market so have been prescribed by doctors for a number of years.

Combination contraceptive pills normally contain 2 messenger substances, progesterone and Estrogen. Nomegestrol Acetate (NOMAC) a progesterone messenger and estroadiol (E2) is the estrogen messenger in the study drug we are testing.

The study will last approximately 7 weeks. This includes a screening visit, in order to assess suitability, up to 6 weeks before the start of the study. Each volunteer will receive one single oral dose of NOMAC-E2 (which contains 2.5mg NOMAC and 1.5mg E2). Each volunteer will be resident 3 days/ 2 nights, after which daily visits are required for a further 4 days. During this time, the volunteer will be monitored: ECG (electric heart recording, at screening and day 6), blood pressure, pulse rate, blood samples and urine samples. The visits are scheduled in such a manner that they allow the adolescent subjects to combine this trial with their school times.

The research and recruitment is being conducted by Richmond Pharmacology Ltd on behalf of Organon.
Duration of study
Years: 2, Months:
Opinion
Favourable
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