Influence of Ribavirin and Interferon on Semen quality

Published: 20-07-2006
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To study the effect of peginterferon alpha and ribavirin on spermatozoa

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34266

Source
ToetsingOnline

Brief title
IRIS-study

Condition

- Hepatic and hepatobiliary disorders
- Sexual function and fertility disorders

Synonym
fertility, semen quality

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Leveronderzoek
Source(s) of monetary or material Support: Stichting Leveronderzoek Rotterdam

Intervention

Keyword: Interferon, Ribavirin, Semen

Outcome measures

Primary outcome

· Assess changes in sperm chromatin structure integrity, sperm concentration,

motility and morphology during ribavirin and peginterferon alpha treatment

Secondary outcome

· Asses if the changes in sperm due to treatment with ribavirin and

peginterferon alpha are reversible

· To assess changes in hormonal status in serum due to treatment with ribavirin

and peginterferon alpha .

Study description

Background summary

During and six months after treatment with peginterferon alpha and ribavirin strict anticonception-use is recommended (the producers advice two reliable forms) for both men and women because ribavirin has teratogenic and/or embryo-lethal effects in animal studies.
In cases of pregnancies during paternal exposure to peginterferon alpha and ribavirin elective termination of the pregnancy is usually recommended. However three cases of births after paternal exposure are reported with no birth defects. Cases of abnormalities after paternal exposure to ribavirin are lacking.
Also studies on the influence of ribavirin on sperm in human are lacking

Study objective

To study the effect of peginterferon alpha and ribavirin on spermatozoa

Study design

Single centre, observational pilot study

Study burden and risks

Burden: time investment (2-2,5 hours) and sampling semen en serum.
Risk: vena punction can cause slight pain, swelling and/or a infection, or a bruise.
Benefit: more infromation on quality of sperm during and after treatment with peginterferon alfa and ribavirin.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

written informed consent

Exclusion criteria

History of known shape and/or motility abnormalities of sperm.
- Concurrent use of drugs influencing sperm shape and motility
- Less then one million spermatozoa/ml in semen at screening

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2006
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-06-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL11719.078.06