A prospective, non-controlled, open-label study to assess the safety and effectiveness of Fibrocaps* in subjects undergoing liver resection.

Published: 28-11-2008
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33792

Source
ToetsingOnline

Brief title
FC-001-Liver resection

Condition

- Hepatobiliary therapeutic procedures

Synonym
Liver resection, liver surgery

Research involving
Human

Sponsors and support

Primary sponsor: ProFibrix

Source(s) of monetary or material Support: ProFibrix

Intervention

Keyword: Fibrin sealant, Liver resection

Outcome measures

Primary outcome

Safety variables include:

• Incidence, nature and severity of adverse events;

• Presence of bile in post-operative drain fluid;

• Changes in vital signs after Fibrocaps*application.

• Changes from baseline in clinical and laboratory values;

• HIV, HAV, HBV and HCV infection rateviral status 12 weeks after treatment;

• Development of Anti-Thrombin Antibodies at 4 and 12 weeks after treatment.

Secondary outcome

Effectiveness parameters include:

• Time to Haemostasis is defined as the absolute time between the start of application of Fibrocaps* and the time when haemostasis is achieved.

• Volume of drain fluid originated atby the wound and not by ascites at 24 and 48 hours post-surgery.

Exploratory parameters:

• Approximate dose of Fibrocaps per cm 2

• Effect of manual pressure application, when applied.

• Effect of the use of generally available materials used for compression, when used.

• Effect of the Fibrocaps*application method

• Validate the prototype application device.

• Other recommendations on the use of the applicator device made by principal

investigators.

Study description

Background summary

Title: A prospective, non-controlled, open-label study to assess the safety and effectiveness of Fibrocaps* in subjects undergoing liver resection.

Background: The intended benefit of Fibrocaps* application is to support local haemostasis, especially in the situations where hemostatic measures based in conventional surgical techniques as suture, ligature or cautery may be ineffective or impractical.

Study objective

The primary objective of this trial is to investigate the safety of Fibrocaps* in subjects undergoing liver resection.
The secondary objective of this study is to investigate the effectiveness of Fibrocaps* on time to achieve haemostasis and volume of drain fluid.
The tertiary objective is to determine the best application method of Fibrocaps* in liver resection using exploratory parameters.

Study design

A phase II, multicentre, multinational, prospective, non-controlled, open-label study in subjects undergoing liver resection.
An estimated 20 subjects will be enrolled to achieve 15 evaluable subjects in no more than 4 sites in Europe.

Intervention

During surgery, Fibrocaps* will be applied as needed to the resected surface. In case bleeding/oozing has not stopped 10 minutes after applying Fibrocaps*, the surgeon will use local standard practice to stop the bleeding/oozing.

Study burden and risks

Fibrocaps* is made from human blood; therefore, it may carry a risk of

transmitting infectious agents. The risk of transmission of an infectious agent has been reduced by screening donors for prior exposure to certain viruses, by testing them for presence of certain current viral infections, and by the inactivation and removal of certain viruses. Despite all these preventive measures, such products may still potentially transmit disease.
There is also the possibility that unknown infectious agents may be present in such products. As with any medicine, drug reactions may occur during treatment with fibrin sealant.
As with any medicine, drug reactions may occur during treatment with fibrin sealant, and all side effects need to be mentioned.
Allergic reactions, in rare cases, have been reported for other fibrin sealants. Signs and symptoms of allergic reactions may include, but are not limited to, burning and stinging at the application site, hives, difficulty in breathing, chills, flushing, headache, low blood pressure, lethargy (sluggish), nausea, restlessness, rapid heartbeats, tightness of the chest, tingling, vomiting and wheezing.
Blood clots in the veins and in the lungs may occur if the fibrin sealant is unintentionally applied into the blood vessel. Although it is very rare, a blood reaction to fibrin sealant components can occur. In addition, tissue adhesion at undesired sites may occur after application of fibrin sealant, if not applied correctly.
As with any experimental product, there may be unexpected side effects. The patient may experience the adverse reactions (unwanted events) listed above or none of these adverse reactions.
Fibrocaps* has not been tested in pregnant women. The medication or treatment used in this study may pose a risk to developing fetuses or to babies who are being breastfed. If the patient becomes pregnant while participating in this study, it is important that she notifies the study doctor immediately. The pregnancy outcome will be followed up to check the the effects of the study procedures on the patient*s health or the baby*s health.
Possible benefits of using Fibrocaps* during liver surgery will be shortening the bleeding time of the operated liver during surgery and thus, decreasing post-operative complications

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

1. Signed the written informed consent form before first screening procedure;
2. Males and females aged >= 18 years and <= 75 years;
3. Scheduled to undergo open liver resection for any reason except trauma;
4. Uses adequate contraception during the course of the study
5. Has a life expectancy of at least one year.
6. Has a normal liver background (absence of extensive fibrosis and cirrhosis)
Intraoperative Inclusion Criteria:
7. Presence of mild or moderate bleeding/oozing which control by conventional surgical techniques, including but not limited to suture, ligature and cautery is ineffective or impractical;
8. Absence of intra-operative complications other than bleeding at the resection site which may, in the opinion of the investigator, interfere with assessment of effectiveness or safety.

Exclusion criteria

1. Pregnant or lactating women and women planning to become pregnant in the 3 months after surgery;
2. Has a known intolerance to blood products or to Fibrocaps components;
3. Unwilling to receive human blood products;
4. Has any psychiatric problems, in the opinion of the investigator, likely to invalidate informed consent;
5. Has a mental or physical condition that would, in the opinion of the investigator, place the subject at an unacceptable risk or render the subject unable to meet the requirements of the

protocol;
6. Unwilling and/or unable to comply with all aspects of the protocol for the duration of the study;
7. a) currently participating or b) has participated in another clinical study involving another IMP within 4 weeks of the start of this trial or c) is planning participation in another clinical trial in the 4 weeks after surgery, which in the opinion of the investigator may interfere with assessment of effectiveness or safety.;
8. Has any other known coagulation disorder which may interfere with the assessment of effectiveness according to the investigator;
9. Child Pugh score B or C;
10. ASAT and/or ALAT > 3 x upper limit normal range;
11. Thrombocytopenia, < 100 x109 PLT/L;
12. APTT > 100 seconds;
13. INR > 2 x upper limit normal range;
14. Use of anticoagulant therapy other than routine prophylaxis for DVT, use of platelet aggregation inhibitors, thrombolytics or anticipated use of these agents after surgery.
15. Treatment with cyclosporine
16. Healthy donors scheduled to undergo liver resection for transplantation purposes.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2009
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Fibrocaps delivery device

Registration:	No
Product type:	Medicine
Brand name:	Fibrocaps
Generic name:	Fibrin Sealant (fibrinogen and thrombin)

Ethics review

Approved WMO Date:	28-11-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-02-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-02-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-07-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-04-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-05-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2008-005857-39-NL
CCMO	NL25368.042.08