The effect of locally applied autologous platelet-rich fibrin sealant on woundhealing

Submission date	Recruitment status No longer recruiting	Prospectively registered		
29/07/2005		☐ Protocol		
Registration date 06/10/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 17/05/2010	Condition category Digestive System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

KF (01) 264835

Study information

Scientific Title

Acronym

The IMPRA-project

Study objectives

Platelet-rich fibrin enhances and accelerates wound healing

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cholelithiasis

Interventions

Surgical wounds treated with trial product (platelet-rich fibrin) or control.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Collagen synthesis

Key secondary outcome(s))

- 1. Woundstrength
- 2. Production of type I and III collagen mRNA
- 3. Histology
- 4. Growthfactors
- 5. Unwanted effects

Completion date

01/09/2006

Eligibility

Key inclusion criteria

Consecutive patients undergoing elective laparoscopic cholecystectomy, over 18 years old who have given written and verbal informed consent.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Not Danish-speaking
- 2. Demential
- 3. Pregnant or lactating women
- 4. Fertile women not using contraception
- 5. Patients on aspirin (acetylsalicylic acid [ASA]) or anticoagulants less than 7 days before surgery
- 6. Patients suffering from anaemia or coagulation disorders
- 7. Patients suffering from incompensated heart or lung disease

Date of first enrolment

01/08/2005

Date of final enrolment

01/09/2006

Locations

Countries of recruitment

Denmark

Study participating centre

Afd. K

Copenhagen Denmark 2400 NV

Sponsor information

Organisation

Vivolution A/S (Denmark)

ROR

https://ror.org/010knjd35

Funder(s)

Funder type

Industry

Funder Name

Vivolution A/S (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2010		Yes	No