ISRCTN34481461 https://doi.org/10.1186/ISRCTN34481461

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

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

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

Primary study design
Interventional

Study design
Randomised controlled trial

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