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

Submission date 29/07/2005	Recruitment status No longer recruiting	Prospectively registered	
29/01/2003		☐ Protocol	
Registration date 06/10/2005	Overall study status Completed	Statistical analysis plan	
		[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

Contact name

Dr Lars Nannestad Jørgensen

Contact details

Afd. K
Bispebjerg Hospital
Bispebjerg Bakke 23
Copenhagen
Denmark
2400 NV
+45 (0)3531 2856
larsnjorgensen@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Collagen synthesis

Secondary outcome measures

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

Overall study start date

01/08/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

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)

Sponsor details

Blokken 45 DK-3460 Birkerod Birkerod Denmark 3460 +45 (0)4581 1962 info@vivolution.com

Sponsor type

Industry

Website

http://www.vivolution.com

ROR

https://ror.org/010knjd35

Funder(s)

Funder type

Industry

Funder Name

Vivolution A/S (Denmark)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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