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

**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 |