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PerClot compared to usual care in gynaecology

Submission date 03/07/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 15/07/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 22/01/2018	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
PerClot is a product that has been developed to control bleeding during surgical procedures or following traumatic injuries. The overall objective of this clinical study is to collect clinical data to demonstrate the safety and effectiveness of PerClot compared to usual care when used during gynecological procedures.

Who can participate?
Women (over 18) having a gynaecological procedure.

What does the study involve?
Half the patients are randomised to receive PerClot. The other half of the patients are randomised to be given usual care which will be whatever treatment the surgeon wishes to use. The time taken for the bleeding to stop is assessed as is whether or not further measures to stop any bleeding that reoccurs after surgery is needed, whether any infection occurs and whether there are any adverse effects to the treatment.

What are the possible benefits and risks of participating?
As this is a post market study on a product already used, there are no associated risks.

Where is the study run from?
Gemelli Hospital, Rome (Italy) and Belvitge Hospital, Barcelona (Spain)

When is the study starting and how long is it expected to run for?
March 2015 to January 2018

Who is funding the study?
CryoLife Europa (UK)

Who is the main contact?
Mrs Kerry McElhinney
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PCT1501.000-C

Study information

Scientific Title
A prospective, multicentre, randomized, safety and effectiveness study of PerClot compared to usual care during gynaecology procedures

Study objectives
To demonstrate the safety and effectiveness of PerClot compared to usual care when used during gynaecology procedures

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Technical and Scientific Ethics Committee, A Gemelli Catholic University of the Sacred Heart, 12/10/2015, Ref 0007342/15
2. Comite Etico de Investgacion Clinica, Hospital Universitari Bellvitge, 15/04/2015, Ref: AC096 /15

Study design
Randomized multicentre trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Gynaecology surgical procedures

Interventions
Half the patients will be randomised to receive PerClot. The dose will be dependent on the surface area and will usually be 3G or 5G. The other half of the patients will be randomised to receive usual care which will be whatever other haemostat the surgeon wishes to use i.e floseal, tisseal etc. If they do not use another haemostat to achieve haemostasis then diathermy may be used as an alternative. Randomisation will be either IWRS (interactive web response system) or IVRS (interactive voice response system).

Intervention Type
Device

Primary outcome measure
Achievement of haemostasis measured in minutes

Secondary outcome measures
Absence of reintervention for post operative bleeding

Overall study start date
01/03/2015

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Subject is over 18
2. Subject is having a gynaecological procedure
3. Subject is willing and able to comply with the protocol
4. Subject is willing and able to give informed consent

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
90

Key exclusion criteria
1. Subject with a history of pelvic or abdominal radiotherapy (within 8 weeks of surgery)
2. Subject is pregnant or actively breastfeeding
3. Subject has a ruptured ectopic pregnancy
4. Subject has a history of abnormal coagulopathy
5. Subject has a sensitivity to starch or starch derived materials
6. Subject has an active or potential infection at the surgical site
7. Subject is currently enrolled in another study

Date of first enrolment
01/10/2015

Date of final enrolment
21/07/2017

Locations

Countries of recruitment
Italy

Spain

Study participating centre
Gemelli Hospital
Rome
Italy
00168

Study participating centre
Belvitge Hospital
Feixa Llarga, s/n

Barcelona
Spain
08907

Sponsor information

Organisation
CryoLife Europa (UK)

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Sponsor type
Industry

ROR
https://ror.org/05972na11

Funder(s)

Funder type
Industry

Funder Name
CryoLife Europa (UK)

Results and Publications

Publication and dissemination plan
Intention to publish in a peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Kerry McElhinney at mcelhinney.kerry@cryolife.com

IPD sharing plan summary

Available on request