Post-operative autologous transfusion of filtered shed blood in total knee arthroplasty: clinical bloodmanagement in everyday orthopaedic practice

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21964

Source
Nationaal Trial Register

Health condition

TKA, transfusion, blood, autoloog

Sponsors and support

Primary sponsor: NA/Orbis
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

Primary outcome:

- Peri-operative Hb levels:

o Standard measurement moments are:

„X Within 24 hours pre-operative. Usually the evening before surgery or the same morning before surgery.

„X One day post-operative

„X Three days post-operative

Secondary outcome

Secondary outcomes:

- Allogeneic blood transfusion in the postoperative period.

The indication for allogeneic blood transfusion and amount of administered blood is registered in the EPD and is available for analysis. In our analysis we will mainly look at necessity of allogeneic blood transfusion in relation to whether a retransfusion system was applied (i.e. dichotomous variables). Differences in the units of packed cells administered will be analysed.

- Length of hospitalisation

o Normal length of stay after TKA is 3-5 days. Data will be collected from the EPD to analyse any prolonged or reduced length of stay. Any prolonged or reduced length of stay will then be analysed to check for possible complications.

- Complications.

o Events that have affected the overall patient outcome, required revision surgery or increased length of stay will be defined as postoperative complications. General non specific complications such as gastrointestinal-, urinary tract-, respiratory- or cardiac complications are not going to be included in the analysis but will be described.

- Amount of autologous blood transfused. The amount of retransfused blood (ml) is registered in our EPD.

Study description

Background summary

This retrospective study will evaluate the efficacy of an ABT system in TKA and compare it to the use of no drain in everyday practice. The primary research question is whether allogeneic blood transfusions are reduced when comparing the use of ABT systems to no use of post-

operative drainage systems. As transfusion triggers tend to vary overtime and between hospitals, the primary outcome will be peri-operative Hb levels. In addition, variables that may have influenced peri-operative blood loss will be measured and analyzed.

Study objective

Allogeneic blood transfusions are reduced when comparing the use of an ABT system to no use of post-operative drains in patients who underwent TKA.

Study design

Pre-, peri and 1, 2 and 3 days post operative HB levels.

Complication rate up to 6 months post operative

Intervention

Total knee arthroplasty (TKA) is associated with considerable blood loss, which may lead to post-operative anemia. To compensate for this blood loss, blood transfusions are sometimes necessary. Although the risks associated with allogeneic blood transfusions, such as transmittable diseases (e.g. HIV, hepatitis C and cytomegalovirus), allergic reactions and immunomodulatory effects are rare and have been minimized over the last years, public expectations are to have a zero-risk blood supply. As a result, alternative blood saving methods have become increasingly popular in treatment and prevention of post-operative anemia. One of these alternative blood saving methods is the use of post-operative draining systems with autologous blood transfusion (ABT). ABT systems have shown controversial results when it comes to decrease in use of allogeneic blood transfusions in TKA.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients undergoing primary TKA

- Surgery between January 2010 and December 2011

Exclusion criteria

- Secondary total knee arthroplasty

- Rheumatoid arthritis (RA)

- Missing data regarding:

a. necessity and amount of autologous blood transfusion

b. necessity of allogeneic blood transfusion

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	18-08-2014
Enrollment:	750
Type:	Anticipated

Ethics review

Positive opinion Date:	11-08-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4561
NTR-old	NTR4729
Other	METC Atrium-Orbis-Zuyd : 14N102

Study results