Trial Review

COVID-19 studies are our top priority. For all other trials, there is a 4-week delay in processing a trial submitted/resubmitted to the ANZCTR and additional delays for updates of registered trials. We appreciate your patience.

VIEW TRIAL AT REGISTRATION VIEW HISTORY

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been endorsed by the ANZCTR. Before participating in a study, talk to your health care provider and refer to this information for consumers

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Trial registered on ANZCTR

Registration number	ACTRN12619000315112
Ethics application status	Approved
Date submitted	26/02/2019
Date registered	28/02/2019
Date last updated	8/10/2019
Date data sharing statement initially provided	28/02/2019
Date results information initially provided	8/10/2019
Type of registration	Prospectively registered

Titles & IDs

Public title	Assessing hypercoagulability after total hip arthroplasty
Scientific title	A retrospective evaluation of hypercoagulability detected by thromboelastography (TEG) in patients undergoing elective total hip arthroplasty who received a TEG as part of standard care.
Secondary ID [1]	None
Universal Trial Number (UTN)	U1111-1229-2715
Trial acronym	None
Linked study record	Not applicable

Health condition

Health condition(s) or problem(s) studied:

Orthopaedic surgery

Total hip arthroplasty

Condition category

Surgery

Anaesthesiology

Blood

Condition code

Other surgery

Anaesthetics

Clotting disorders

Intervention/exposure

Study type

	Observational
Patient registry	False
Target follow-up duration	
Target follow-up type	
Description of intervention(s) / exposure	This retrospective observational study will include the records of patients who have undergone elective total hip arthroplasty under general and spinal anaesthesia who have had a thromboelastograph done as part of routine clinical care. We aim to review thromboelastograph from the time of surgery until patient discharge. As this is a retrospective audit of the medical records, no patient involvement is required. Patients will not be contacted in any way, and all information extracted from the records will be de-identified and aligned with hospital governance processes for clinical audit and retrospective data collection.
Intervention code [1]	Early Detection / Screening
Comparator / control treatment	For patients who have undergone elective total hip arthroplasty who have had a thromboelastograph done as part of routine care, we will compare the thromboelastograph in patients who have had their surgery performed under general anaesthesia to those who have had their surgery performed under spinal anaesthesia.
Control group	Active

Outcomes

Primary outcome [1]	The development of a hypercoagulable state as evident by the maximum amplitude (measured in millimeters). This information will be obtained by reviewing the medical records. There is no patient contact at any point.
Timepoint [1]	From the time of surgery to hospital discharge.
Secondary outcome [1]	The development of a hypercoagulable state as evident by the R-time (measured in minutes) on the thromboelastograph. This information will be obtained by reviewing the medical records. There is no patient contact at any point.
Timepoint [1]	From the time of surgery to hospital discharge.
Secondary outcome [2]	The development of a hypercoagulable state as evident by the K-Time (measured in minutes) on the thromboelastograph. This information will be obtained by reviewing the medical records. There is no patient contact at any point.
Timepoint [2]	From the time of surgery to hospital discharge.
Secondary outcome [3]	The development of a hypercoagulable state as evident by the Alpha Angle (measured in degrees) on the thromboelastograph. This information will be obtained by reviewing the medical records. There is no patient contact at any point.
Timepoint [3]	From the time of surgery to hospital discharge.
Secondary outcome [4]	The development of a hypercoagulable state as evident by the clot lysis at 30 minutes on the thromboelastograph. This is measure by the amplitude of the thromboelastograph at this time point. This information will be obtained by reviewing the medical records. There is no patient contact at any point.
Timepoint [4]	From the time of surgery to hospital discharge.

Eligibility

Key inclusion criteria	Adult patients (age greater 18 years), undegoing elective primary total hip arthoplasty under a general or spinal anaesthetic
Minimum age	18 Years
Maximum age	No limit
Gender	Both males and females
Can healthy volunteers participate?	No
Key exclusion criteria	Emergency hip arthroplasty Patients who have not had a thromboelastogram performed as part of routine clinical care

Study design

Purpose	Natural history
Duration	Longitudinal
Selection	Defined population
Timing	Retrospective
Statistical methods / analysis	Given that this is a retrospective audit, simple descriptive statistics will be performed. For non-normally distributed data we will use non-parametric statistical analysis (Friedman's test) followed by the Wilcoxon signed rank test with Bonferroni correction to evaluate changes in TEG over time in each group. We will

use the Mann-Whitney U test to compare data between patients having general anaesthesia and patients having spinal anaesthesia at any given sampling time point. Data will be enteredas medians with quartiles. A $p < 0.05$ will be considered statistically significant.

Recruitment

Recruitment status Completed

Date of first participant enrolment

Anticipated 1/03/2019 **Actual** 8/04/2019

Date of last participant enrolment

Anticipated 10/03/2019 **Actual** 27/05/2019

Date of last data collection

Anticipated 10/03/2019 **Actual** 3/06/2019

Sample size

Target 52 **Accrual to date** **Final** 52

Recruitment in Australia

Recruitment state(s) VIC

Recruitment hospital [1] Austin Health - Austin Hospital - Heidelberg

Recruitment hospital [2] Austin Health - Heidelberg Repatriation Hospital - Heidelberg West

Recruitment postcode(s) [1] 3084 - Heidelberg

Funding & Sponsors

Funding source category [1] Hospital

Name [1] Austin Health

Address [1] 145 Studley Road, Heidlelberg, 3084, Victoria, Australia

Country [1] Australia

Primary sponsor type Hospital

Name Austin Health

Address 145 Studley Road, Heidlelberg, 3084, Victoria, Australia

Country Australia

Secondary sponsor category [1] None

Name [1]

Address [1]

Country [1]

Ethics approval

Ethics application status Approved

Ethics committee name [1] Austin Health Research Ethics Commitee

Ethics committee address [1] 145 Studley Road, Austin Health, Heidlelberg, 3084, Victoria, Australia

Ethics committee country [1] Australia

Date submitted for ethics approval [1] 25/02/2019

Approval date [1] 05/04/2019

Ethics approval number [1] LNR/19/Austin/21

Summary

Brief summary This retrospective observational study will be conducted by the Department of anaesthesia.

Total hip arthroplasty (THA) can result in a significant surgical stress, which in turn can trigger a hypercoagulable state. These patients are at significant risk for the development of thromboembolic complications. Despite venous thromboembolism (VTE) chemoprophylaxis being administered to all patients who undergo THA at Austin Health, VTE remains a common cause of preventable death and a

well recognised complication after total THA. Despite combining extended VTE chemoprophylaxis with early mobilization, compression stockings and intermittent pneumatic compression devices, many patients at Austin Health who undergo THA remain at high risk for VTE because of advanced age, extensive surgical procedures, and greater medical comorbidities. Furthermore, a large multicenter study showed that most VTE's occur due to prophylaxis failure rather than failure to provide prophylaxis. Although several agents have been shown to reduce the risk of thromboembolic disease, there is no clear preference for thromboembolic chemoprophylaxis for patients undergoing elective total hip arthroplasty.

Thromboelastography (TEG) measures whole blood coagulation and fibrinolysis providing a global view of the interaction between all components of clot formation, retraction and lysis. TEG is one of the most sensitive methods currently available for the assessment of a perioperative hypercoagulable state with numerous reports in surgical patients demonstrating an association between TEG measured variables, anaesthetic techniques, and postoperative thrombotic events. Studies have demonstrated that major joint arthroplasty is associated with activation of coagulation (hypercoagulable state) as measured by TEG, however there have been few comparisons of the effects of general and regional anaesthesia techniques on coagulation.

Therefore, we propose to perform a retrospective audit of patients who underwent THA at Austin Health, who received a TEG as part of routine care.

The primary aims of this retrospective review are to determine if VTE chemoprophylaxis with low molecular weight heparin prevents hypercoagulability after THA (as assessed by TEG) and if general or spinal anaesthesia had similar effects on perioperative coagulability as measured by TEG.

Notably, there will be NO CLINICAL or patient contact at any point. All data collected has already been collected as part of routine clinical care according to standard anaesthesia and surgical processes. No new data will be collected.

Trial website	Not applicable
Trial related presentations / publications	
Public notes	

Contacts

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Data sharing statement

Will individual participant data (IPD) for this trial be available (including data dictionaries)?	No

No/undecided IPD sharing reason/comment	This is a retrospective study and a non international study
What supporting documents are/will be available?	No other documents available

Summary results

Have study results been published in a peer-reviewed journal?	No

Other publications

Have study results been made publicly available in another format?	

Results – basic reporting

Results – plain English summary

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