Impact of pharmacist educational interventions on patients with anticoagulants

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Main Information

Primary registry identifying number
LBCTR2020033424

Protocol number
LAU.SOP.LK2.11/Jul/2017

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
LBCTR did not exist/was available at the start of the study

Date of registration in national regulatory agency
06/03/2020

Primary sponsor
Lebanese American University

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
16/03/2020

Date of registration in national regulatory agency
06/03/2020

Public title
Impact of pharmacist educational interventions on patients with anticoagulants

Acronym
N/A

Scientific title
Impact of pharmacist-conducted anticoagulation patient education and telephone follow-up on transitions of care: A randomized controlled trial

Acronym
N/A

Brief summary of the study: English

This was a randomized, non-blinded interventional study conducted at a tertiary care teaching hospital in Beirut, Lebanon. Participants were inpatients ≥ 18 years, discharged on a therapeutic dose of anticoagulant.
Patients were randomized by block randomization. The control group received the standard anticoagulant discharge counseling provided by nurses. The intervention group was counseled by a pharmacist. All patients received a phone call from the study investigators at day at day 30 post-discharge. Patients counseled by pharmacists received an additional phone call at day 2 to 3. Primary outcome measures included readmission rates within 30 days post-discharge and bleeding events. Secondary outcomes included unplanned patient contact with prescribers post-discharge.

Brief summary of the study: Arabic

إن المعيار المعتمد حالياً في المستشفى يقضي بتوفير المرضى وعائلاتهم بالمعلومات اللازمة عن الأدوية الموصوفة بعد خروجهم من المستشفى. كل مقدمي الرعاية الصحية بما في ذلك الممرضين والأطباء والصيادلة متمرسون في توفير المعلومات المطلوبة عن الأدوية. نحن نرغب في تقييم أثر المعلومات الموفرة من قبل الصيادلة قبل مغادرة المرضى المستشفى حول الأدوية المسيلة للدم وخلال فترة المتابعة من 2الى 3 بعد مغادرة المستشفى خصوصاً بما يخص مخرجات السلامة كالنزيف30أيام بعد مغادرة المستشفى وفي اليوم .

Health conditions/problem studied: Specify

The most common indication for anticoagulation was atrial fibrillation, venous thromboembolism, aortic valve replacement, and mitral valve

replacement

Interventions: Specify

Patients were randomized by block randomization. The control group received the standard anticoagulant discharge counseling provided by nurses. The intervention group was counseled by a pharmacist. All patients received a phone call from the study investigators at day at day 30 post-discharge. Patients counseled by pharmacists received an additional phone call at day 2 to 3.

Key inclusion and exclusion criteria: Inclusion criteria

Participants were inpatients ≥18 years discharged on an oral anticoagulant for treatment

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

58

Key inclusion and exclusion criteria: Age maximum

86

Key inclusion and exclusion criteria: Exclusion criteria

Excluded were those with severe cognitive impairment, inability to communicate or to be followed-up, discharged on an anticoagulant for prophylaxis.

Type of study

Interventional

Type of intervention

Educations programs

Type of intervention: Specify type

N/A

Trial scope

Safety

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Open (masking not used)

Study design: Control

Active

Study phase

N/A

Study design: Purpose

Health services research

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

Anticoagulants

Therapeutic indication

The most common indication for anticoagulation was atrial fibrillation, venous thromboembolism, aortic valve replacement, and mitral valve replacement

Therapeutic benefit

N/A - studied readmission rates

Study model
N/A

Study model: Explain model
N/A

Study model: Specify model
N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention
None retained

Biospecimen description
N/A

Target sample size
200

Actual enrollment target size
200

Date of first enrollment: Type
Actual

Date of first enrollment: Date
01/08/2017

Date of study closure: Type
Actual

Date of study closure: Date
31/07/2019

Recruitment status
Complete

Recruitment status: Specify

Date of completion
31/07/2019

IPD sharing statement plan
No

IPD sharing statement description
N/A

Additional data URL
None

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
N/A	N/A

Sources of Monetary or Material Support

Name
N/A

Secondary Sponsors

Name
N/A

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Lamis Karaoui	Lebanese American University - School of Pharmacy, Byblos	Lebanon	+961-354-7254 ext 2318	lamis.karaoui@lau.edu.lb	Lebanese American University
Scientific	Nibal Chamoun	Lebanese American University - School of Pharmacy, Byblos	Lebanon	+961-345-7254 ext 24017	nibal.chamoun@lau.edu.lb	Lebanese American University

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Lebanese American University - Medical Center Rizk Hospital	Lamis R. Karaoui	Pharmacist/Clinical Associate Professor	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Lebanese American University- University Medical Center Rizk Hospital	11/07/2017	Christine Chalhoub	christine.chalhoub@lau.edu.lb	+961 9 547254 ext. 2340

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Anticoagulation	2-Propanol (T51.2)	Anticoagulation

Interventions

Intervention	Description	Keyword
Patients were randomized into 2 groups.	The control group received the standard anticoagulant discharge counseling provided by nurses. The intervention group was counseled by a pharmacist. All patients received a phone call from the study investigators at day at day 30 post-discharge. Patients counseled by pharmacists received an additional phone call at day 2 to 3.	postdischarge counseling

Primary Outcomes

Name	Time Points	Measure
Readmission rates and any bleeding event	day 3 and day 30 post-discharge	Number of patients readmitted at day 3 and day 30 post discharge

Key Secondary Outcomes

Name	Time Points	Measure
Documented elements of education in the medical record and reported mortality	30 days post-discharge follow-up	number of patients receiving elements of education

Trial Results

Summary results

200 patients were included with 100 patients in each group. Baseline characteristics were similar between the two groups ($p > 0.05$). More patients in the pharmacist-counseled group contacted their physician within 3 days (14% versus 4%; p=0.010). No statistically significant difference in bleeding rates at day 3 and day 30 post-discharge between the two groups was observed. The documentation in the pharmacist-counseled group was better ($p < 0.05$), and more explicit education documents were provided by the pharmacist-counseled group ($p < 0.001$). Patients in the standard of care group were more aware of their next appointment date with the physician compared to the pharmacist-counseled group (52% versus 31%, $p < 0.001$).

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files