

ANTICOAGULAZIONE

Attualità cliniche e di laboratorio. Aspetti sociali

BOLOGNA 25-26 GENNAIO 2018

Stato attuale del FADOI-START

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Real-life data VTE

Acute Treatment of Pulmonary Embolism with Rivaroxaban - Real Life Data from the Prospective Dresden NOAC Registry (NCT01588139)

Adrian C. Smith, S. Calberka, V. Khorin et al., TASC, Swiss Heart, Dresden, Germany

	ITT	ITT	ITT	ITT	ITT
	n=100	n=100	n=100	n=100	n=100
Age (years)	61	62	61	62	61
Male (%)	76	76	76	76	76
Weight (kg)	76	76	76	76	76
Height (cm)	173	173	173	173	173
BMI (kg/m ²)	25.2	25.2	25.2	25.2	25.2
Time to discharge (days)	1	1	1	1	1
Time to hospital discharge (days)	1	1	1	1	1
Time to home (days)	1	1	1	1	1
Time to return to normal activities (days)	1	1	1	1	1
Time to return to work (days)	1	1	1	1	1
Time to return to normal diet (days)	1	1	1	1	1
Time to return to normal sexual activity (days)	1	1	1	1	1
Time to return to normal driving (days)	1	1	1	1	1
Time to return to normal travel (days)	1	1	1	1	1
Time to return to normal sports (days)	1	1	1	1	1
Time to return to normal social activities (days)	1	1	1	1	1
Time to return to normal work (days)	1	1	1	1	1
Time to return to normal life (days)	1	1	1	1	1

ClinicalTrials.gov

Search for studies

Home > Find Studies > Search Results > Study Record Detail

Treatment of VTE with Rivaroxaban or Current Standard of Care Therapy (SALU)

This study is ongoing, but not recruiting participants.

Study ID: NCT01588139

Study Title: Treatment of an Acute Deep Vein Thrombosis (DVT) With Either Rivaroxaban or Current Standard of Care Therapy (SALU)

Study Type: Randomized Controlled Trial

Study Status: Recruiting

Study Location: Dresden, Germany

Study Dates: 2012 to 2018

Study Sponsor: Swiss Heart

Study Funding: Swiss Heart

Study Description: This study is a prospective, randomized, controlled trial comparing the efficacy and safety of rivaroxaban versus current standard of care therapy for the treatment of acute deep vein thrombosis (DVT) in outpatients.

CCRN 2498 (Venous Thromboembolism)

PREFER in VTE Prevention of Thromboembolic Events - European Registry in Venous Thromboembolism

Specialty: Cardiovascular (Co-ordinated by Haematology, Internal Medicine)

Portfolio Eligibility: Adopted commercial study

Study Type: Observational

Design Type: Not specified

Disease(s): Non-malignant haematology (Injuries and Emergencies)

Phase: N/A

Lead Country: England (also active in Scotland and Northern Ireland and Wales)

Main Inclusion Criteria:

- Female or male patients, at least 18 years old
- Established acute first-time (initial) or recurrent VTE
- Hospitals or specialised centres (surgical, non-surgical, acute or office-based outpatient)
- Written informed consent for participation in the registry and to provide telephone details for follow-up
- Not simultaneously participating in a double blind interventional study

Main Exclusion Criteria:

- There are any specific exclusion criteria, providing selection criteria are met.

VTE Garfield

global anticoagulant registry in the field



In Italia?

START-Register

<http://www.start-register.org>

The screenshot shows the homepage of the START-Register website. At the top, there is a blue header with the text "START - Register" and "SURVEY ON ANTICOAGULATED PATIENTS - REGISTER". Below this, a navigation bar contains links for "Home", "Area riservata partecipanti", "Chi siamo", "Contatti", and "Partecipa al registro", with the last one circled in red. The main content area features a "START-SSC" button and a section titled "Il Registro START" with sub-sections for "Razionale", "Registro", "Disegno", and "Obiettivi e durata".

3° CONVEGNO DI ANTICOAGULAZIONE.it

“ ANTICOAGULAZIONE | Attualità cliniche e di laboratorio. Aspetti sociali ”

BOLOGNA 25-26 GENNAIO 2018 Savoia Hotel Regency - Via del Pilastro 2, 40127 Bologna

Perchè un altro registro?



- 350 Reparti di Medicina Interna (o Geriatria) in tutta Italia
- 2700 Soci (40% under 40)

Obiettivi

- Raccogliere Informazioni Real World sull'efficacia e la sicurezza dei DOACs nei pazienti con Trombosi Venosa Profonda ed Embolia Polmonare in gruppi di pazienti poco rappresentati negli studi di fase III e negli studi post marketing
- Migliorare la gestione di questi pazienti (scopo educativo societario)



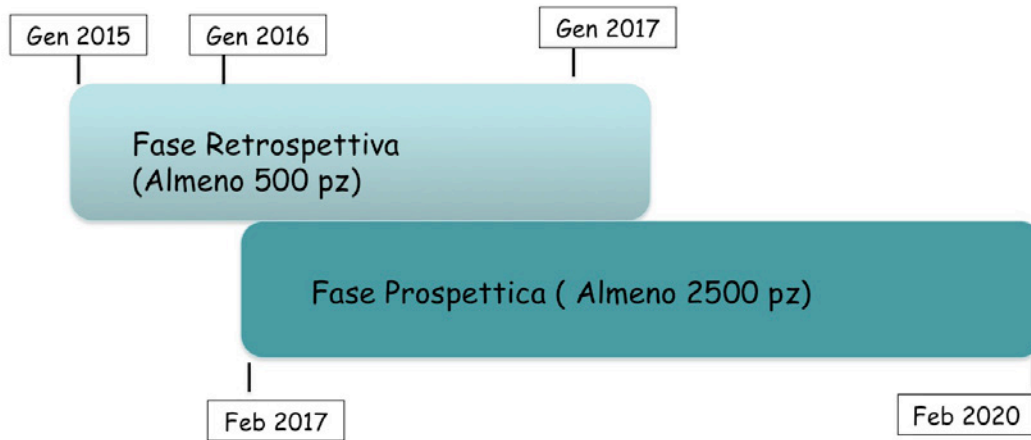
Partecipante	
Codice	ASO Nome Angiology Comune ()
Arruolamento	
Identificativo paz.	qqq
Data Inserimento	25-09-2015 Ultimo follow-up
Cod.START	ASO-qqq
Data di nascita	02-12-1975 Età 39
Sesso	<input checked="" type="radio"/> M <input type="radio"/> F
Età all'arruolamento	39
Status	Attivo
Causate	
Terapia	Axaraban (Eliquis)
Posologia Apixaban	5 mg 2/die
Dose (mg/die)	10
Data inizio terapia	15-09-2015
Preced. Terapia AVK	Coumadin Mesi AVK 1
Indicazioni cliniche	
Patologia	Tromboembolia Venosa
Peso	Kg
Altezza	cm
BMI	g
Hb	109
GR	103
Plastrine	103
Creatinina	mg/dl
Clearance Creat.	ml/min
Trans. ALT	
Trans. AST	
Tromboembolia venosa (TEV)	
TVP	<input checked="" type="radio"/> No <input type="radio"/> Sì
Embolia Polmonare	<input checked="" type="radio"/> No <input type="radio"/> Sì
TVS	<input checked="" type="radio"/> No <input type="radio"/> Sì
Natura evento	<input checked="" type="radio"/> Idiopatico <input type="radio"/> Secondario
Fattori di rischio	
Altri eventi pregressi	<input checked="" type="radio"/> No <input type="radio"/> Sì
Patologie associate	
Storia di tumore	<input type="radio"/> No <input type="radio"/> Sì
Tumore attivo	<input type="radio"/> No <input type="radio"/> Sì
Chemio-radioterapia in atto	<input type="radio"/> No <input type="radio"/> Sì
Diabete	<input type="radio"/> No <input type="radio"/> Sì
Iperensione	<input type="radio"/> No <input type="radio"/> Sì

Registro FADOI/START

- Pazienti con TEV (TVP/EP)
- Trattati con DOAC
- Retrospektivo/prospettico
- Referenti regionali
- Coordinamento Centro Studi FADOI

Farmaci	DOACs
Indicazione	Solo TVP (anche arti superiori) e EP, NO Fibrillazione Atriale, TEV sedi atipiche, TVS
Setting	Ospedaliero/Ambulatoriale, prevalentemente ospedaliero per le EP
Durata del follow up	Max 3 anni. Fino a terapia attiva più 3 mesi dal termine della terapia
Visite di follow up	Libere, minimo 2 all'anno

Timeline



Registro FADOI/START

1355 pazienti trattati con i DOAC per TEV acuto



Circa 50% EP



103 pazienti trattati con Dabigatran
312 pazienti trattati con Apixaban
868 pazienti trattati con Rivaroxaban
72 pazienti trattati con Edoxaban

Registro FADOI/START

1355 pazienti trattati con i DOAC per
TEV acuto (54% unprovoked)



15 recidive di TEV segnalate



9 durante terapia con DOAC
6 dopo la sospensione del farmaco

Registro FADOI/START

1355 pazienti trattati con i DOAC per
TEV acuto



59 eventi emorragici segnalati



9 maggiori (1 intracranico)
8 non maggiori clinicamente rilevanti
42 minori

Registro FADOI/START

1355 pazienti trattati con i DOAC per
TEV acuto



9 decessi

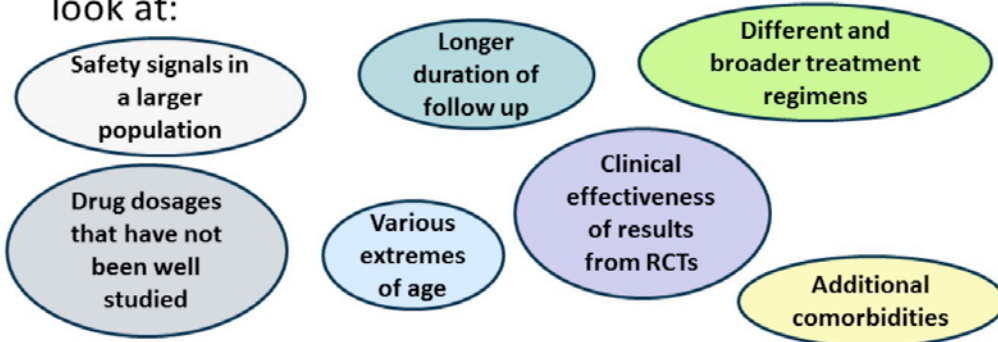


2 probabilmente correlati al TEV

Grazie per l'attenzione !!!

Randomized Controlled Trials and Real-World Data: How Do They Differ?

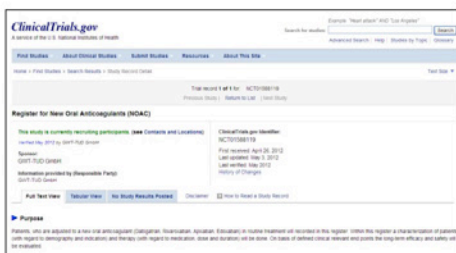
- RCTs test the efficacy of a drug in ideal circumstances with strict inclusion/exclusion criteria
- Real world data complements RCTs by allowing us to look at:



Hannan EL. *J Am Coll Cardiol Intv.* 2008;1:211-217.
 Sørensen HT. *Hepatology.* 2006;1075-1082.

Real-life data AF

Dresden NOAC Registry



Mini Sentinel (FDA)

Analysis	Dabigatran			Warfarin		
	No. of Patients	No. of Events	Incidence no. of events/ 100,000 days at risk	No. of Patients	No. of Events	Incidence no. of events/ 100,000 days at risk
Gastrointestinal hemorrhage						
Analysis with required diagnosis of atrial fibrillation	10,599	16	1.6	43,341	160	3.5
Sensitivity analysis without required diagnosis of atrial fibrillation	12,195	19	1.6	119,940	338	3.1
Intracranial hemorrhage						
Analysis with required diagnosis of atrial fibrillation	10,587	8	0.8	43,594	109	2.4
Sensitivity analysis without required diagnosis of atrial fibrillation	12,182	10	0.9	120,020	204	1.9

Gloria AF registry

Results of the 1st Phase of the International GLORIA-AF Registry Program: Regional Treatment Differences Before the Era of Novel Anticoagulants

MV Huisman, CS Ma, HC Diener, SJ Dubner, JL Halperin, KJ Rothman, C Teutsch, A Clemens, K Zint, E Kleine, DB Bartels, **GYH Lip** for the GLORIA-AF Investigators

Global Registry on Long-Term Oral Antithrombotic Treatment in Patients with Atrial Fibrillation

Danish Registry

