

日本医師会治験促進センター 「臨床試験登録システム」

社団法人 日本医師会 治験促進センター

2007.9.21

第1回 臨床研究登録情報検索ポータルサイト運営委員会

これまでの経緯と現状

- ◆厚生労働省の要請を受けてウェブサイトを構築
- ◆対象は医師主導治験（医薬品・医療機器）と企業治験（医療機器）
- ◆現在は治験促進センターが支援してきた医師主導治験が主
- ◆登録臨床試験数は12*

* : 2007.9.11現在 ²

ICMJEの認定を受けるために

- ◆ WHOが示す基準に準拠するよう、2006年大幅改定(情報のXML形式によるダウンロードも可能)
- ◆ 改定したウェブサイトをもとにICMJE(医学雑誌編集者国際委員会)に認定を申請(2007.2)
- ◆ ICMJEが方針変更(ICMJE独自での認定ではなく、WHOに一任)(2007.4)

JMACCT CTRへの臨床試験登録の方法

研究者からの登録依頼を受けて掲載に

必要な情報を入手



掲載案を治験促進センターが作成し、研究者に提案



適宜修正等の上、公開

WHOの求める事項を満たした質の高い内容を掲載

掲載数がある程度増えた段階で
研究者が入力する形式に移行予定

JMACCT CTR リスト画面



Clinical Trial Registration

Japan Medical Association, Center for Clinical Trials



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- CTR**
- Glossary
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- References
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CTR List

SeqNo.	Official scientific title of the study	Title of the study (Brief title)	Region
1	Open-Label Trial to Evaluate the Efficacy and Safety of the Use of Argatroban in Patients With Heparin-Induced Thrombocytopenia	ARG-HIT-CVD	Japan dataset
2	A phase III efficacy and safety study of phenobarbital sodium injection in newborns with neonatal convulsion	A phase III efficacy and safety study of phenobarbital sodium injection in newborns with neonatal convulsion	Japan dataset
3	Phase2 Study of Glivec (imatinib mesylate, formerly known as ST1571) in Patients with Relapsed or Refractory Sarcomas with c-kit or PDGFR Expression	CST1571BJP04	Japan dataset
4	Phase I-II clinical trial of irinotecan hydrochloride (CPT-11) for refractory pediatric solid tumors	CPT-PED-05	Japan dataset
5	J-BAF study Evaluation of the efficacy and safety of Bepridil hydrochloride in the conversion of persistent atrial fibrillation. A placebo-controlled, randomized,	JBEP-DBT	Japan dataset

JMACCT CTR 個別情報画面



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Dataset

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Basic information

Official scientific title of the study	Open-Label Trial to Evaluate the Efficacy and Safety of the Use of Argatroban in Patients With Heparin-Induced Thrombocytopenia
Title of the study (Brief title)	ARG-HIT-CVD
Region	Japan

Condition

Condition	Heparin-Induced Thrombocytopenia
Classification by specialty	Cardiology
Classification by malignancy	Others
Genomic information	no

Objectives

The purpose of the study is to evaluate efficacy and safety of argatroban in the patients with heparin-induced thrombocytopenia (HIT)/ HIT and thrombosis syndrome (HITTS). This multi-center trial covers mainly the patients with cardiovascular diseases. Subjects are included in the trial when they are clinically diagnosed of HIT/HITTS. Initial dose of argatroban