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Safety and efficacy of landiolol in controlling heart rate of supraventricular tachyarrhythmias in patients with severe sepsis

Submission date 27/09/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 10/12/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/12/2013	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aim
Supraventricular tachyarrhythmias (abnormal heart rhythm when the heart beats faster) are frequently observed in patients with sepsis. The incidence of paroxysmal atrial fibrillation /flutter (PAF) has been reported to be 31% in critically ill patients with sepsis. Tachyarrhythmias have been identified as a major source of morbidity in critically ill patients. Therefore, controlling tachyarrhythmia is important in such patients. Drugs used to control the heart rate include beta-blockers. The aim of this study is to assess if a drug called landiolol can safely and effectively control heart rate of supraventricular tachyarrhythmias in patients with severe sepsis.

Who can participate?
All patients admitted to the intensive care unit (ICU) of the Kanazawa University Hospital from January 2006 to December 2011.

What does the study involve?
Patients were randomly allocated to one of two groups: those treated with landiolol (landiolol group) and those not treated with landiolol (control group).

What are the possible benefits and risks of participating?
The possible benefit is that patients can get hemodynamic stabilization. On the other hand, the possible risks are bradycardia (slower than usual heart beat) and shock. Should that happen, we stop giving landiolol to participants.

Where is the study run from?
Intensive Care Unit in Kanazawa University Hospital (Japan)

When is the study starting and how long is it expected to run for?
From January 2006 to December 2011.

Who is funding the study?
Investigator initiated and funded and no external funding (Japan)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Safety and efficacy of landiolol in controlling heart rate of supraventricular tachyarrhythmias in patients with severe sepsis: a randomized controlled study

Study objectives
Landiolol can safely and effectively control heart rate of supraventricular tachyarrhythmias in patients with severe sepsis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Innovative Clinical Research Center, Kanazawa University (iCREK); September/11/2009; Ref 5576

Study design
Historical cohort single-center inter-subjective comparison study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Supraventricular tachyarrhythmias with sepsis

Interventions
Patients were divided into two groups: those treated with landiolol (landiolol group) and those not treated with landiolol (control group) to control HR of supraventricular tachyarrhythmias.

Patient characteristics and hemodynamics of the two groups were compared using an independent t-test for continuous variables and with either Fishers exact test or a chi-square test for categorical variables. Other data were analyzed by repeated-measures analysis of variance. In all analyses, $p < 0.05$ was considered statistically significant.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Landiolol

Primary outcome measure
HR reduction of the supraventricular tachyarrhythmias without a decrease in arterial pressure. Arterial pressure and HR were compared between the two groups at 1, 8, and 24 h after the initiation of tachyarrhythmia.

Secondary outcome measures
The frequency of conversion to sinus rhythm. Differences of conversion rates were analyzed with Fishers exact test or the chi-square test as appropriate.

Overall study start date
11/09/2009

Completion date

31/03/2012

Eligibility

Key inclusion criteria
1. All patients who admitted to intensive care unit of the Kanazawa University Hospital from January 2006 to December 2011
2. Systemic inflammatory response syndrome score ≥ 2 with infection
3. Supraventricular tachyarrhythmias with HR ≥ 120 bpm for >1 h

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
61

Key exclusion criteria
1. Less than 18 years old
2. History of chronic supraventricular tachyarrhythmias
3. Supraventricular tachyarrhythmias at the time of ICU admission

Date of first enrolment
11/09/2009

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Japan

Study participating centre
3-7 Takaramachi
Kanazawa
Japan
9200934

Sponsor information

Organisation
Kanazawa University Hospital (Japan)

Sponsor details
13-1, Takaramachi
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Sponsor type
Hospital/treatment centre

Website
http://web.hosp.kanazawa-u.ac.jp/

ROR
https://ror.org/00xsdn005

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Japan)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration