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The BioVent - BIOmarkers for mechanically VENTilated patients cohort study

Submission date	Recruitment status	[_] Prospectively registered
05/07/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/10/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2023	Respiratory	

Plain English summary of protocol

Background and study aims
The predictive properties of biomarkers in critical care are promising. However, there are few studies and most prospective studies are restricted to specific diseases. The aim of this study is to explore predictors of outcomes in mechanically ventilated patients; to assess short-term and long-term outcomes of mechanically ventilated patients; to identify major events during mechanical ventilation; to identify chronic diseases associated with poor outcomes; to analyze the potential and verify previous results of circulating biomarkers for prognostication in mechanically ventilated patients, patients with ventilator-associated pneumonia and patients with prolonged mechanical ventilation

Who can participate?
Critically ill patients requiring invasive mechanical ventilation for at least 12 hours.

What does the study involve?
This is an observational study. The study does not interfere with treatment. Besides additional blood sampling no interventions are planned. Patients will be assessed at study inclusion, after two, four days, at ICU discharge, at hospital discharge and after one year. Further assessments are scheduled if ventilator-associated pneumonia is suggested or the patient is continuously on invasive mechanical ventilation for 21 days.

What are the possible risks and benefits of participating?
Patients do not experience any direct benefits from the study. However, they contribute to the improvement of medical knowledge in the field. Patients are exposed to a marginal increased risk of anaemia, due to additional blood sampling (approx. 30ml blood, at most 100ml blood during the whole study).

Where is the study run from?
University Hospital Basel, Clinic of Pulmonary Medicine and Respiratory Cell Research (Switzerland)

When is the study starting and how long is it expected to run for?
The study started in 2011 and is expected to last four and half years. The trial will be recruiting participants for approximately three and an half years

Who is funding the study?
University Hospital Basel, Clinic of Pneumology and Respiratory Cell Research. Unrestricted grants are provided by the Gottfried und Julia Bangerter-Rhyner Foundation, University Basel and Freie Akademische Foundation (Switzerland).

Who is the main contact?
Prof. Daiana Stolz

Contact information

Type(s)
Scientific

Contact name
Prof Daiana Stolz

Contact details
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Basel
Switzerland
4031

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prospective, multicentric, longitudinal study to determine predictors of outcome in mechanically ventilated critically ill patients

Acronym
BioVENT

Study objectives

Circulating biomarkers are able to reliably identify patients with poor outcomes among a critically ill population requiring mechanical ventilation in medical and surgical ICUs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Basel Ethics Committee (Ethikkomission beider Basel 03/2010), Ref.Nr EK 75/10
2. Bellinzona Ethics Committee (Comitato etico cantonale Bellinzona) 12/2011, Rif.CE 2519
3. Lausanne Ethics Committee (Commission cantonale dethique Lausanne) 03/2011, Protocole 65 /11
4. Medical University of Vienna Ethics Committee (Ethikkomission der Medizinischen Universität Wien) 01/2012, EK Nr. 946/2011
5. Zurich Ethics Committee (Kantonale Ethik-Komission Zürich) 01/2012, KEK-ZH-Nr. 2011-0326
6. Ile de France VI Ethics Committee (Comité de Protection des Personnes Ile de France VI)

Study design
Investigator initiated and driven prospective observational multicentric longitudinal study

Primary study design
Observational

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Other

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
Critically ill patients on invasive mechanical ventilation

Interventions
Visit day 0: assessment of baseline characteristics, vitals, venous puncture, subjective estimation of outcome
Visit day 2: vitals, venous puncture, subjective estimation of outcome
Visit day 4: vitals, venous puncture, subjective estimation of outcome
Visit ICU discharge: assessment of complications during ICU stay
Visit hospital discharge: assessment of survival
Visit 1 year: assessment of survival
Visit VAP (if patient develops ventilator associated pneumonia during ICU stay): assessment of VAP parameters, vitals, venous puncture, subjective estimation of outcome
Visit VAP day 4 (four days after development of ventilator associated pneumonia): vitals, venous puncture, subjective estimation of outcome

Visit PMV (if patient on invasive mechanical ventilation for 21 days, prolonged mechanical ventilation) day : vitals, venous puncture, subjective estimation of outcome

Follow-up duration: 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Crude mortality within 28 days

Secondary outcome measures
1. Mortality within one year
2. Duration of ICU and hospital stay
3. Duration of mechanical ventilation, ventilation free days, weaning attempts, survival in the subgroups of mechanically ventilated patients, events during mechanical ventilation

Endpoints will be obtained during ICU stay or at scheduled assessments.

Overall study start date
01/04/2011

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Critically ill patients at the start of invasive mechanical ventilation
2. Estimated to require continuous ventilatory support for longer than 24 hours or if already ventilated for 12 to maximal 36 hours.
3. 18 years of age or older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000 (500 derivation cohort, 500 confirmation cohort)

Total final enrolment
961

Key exclusion criteria
1. Pregnancy
2. Patients with pre-existing mental disorder precluding proper informed consent

Date of first enrolment
01/04/2011

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Austria

France

Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital of Basel

Sponsor details
Dept of Pneumology
Petersgraben 4
Basel
Switzerland
4031

Sponsor type
Hospital/treatment centre

Website
http://www.unispital-basel.ch/

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsspital Basel

Alternative Name(s)
University Hospital Basel, University Hospital of Basel, The University Hospital Basel, Hôpital Universitaire de Bâle, L'Hôpital universitaire de Bâle, Das Universitätsspital Basel, UHB

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Switzerland

Funder Name
Gottfried und Julia Bangerter-Rhyner-Stiftung (Switzerland)

Funder Name
Universität Basel

Alternative Name(s)
UniBas, University of Basel, Universitas Basiliensis, Die Universität Basel, UB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Funder Name
Freie Akademische Stiftung (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/04/2023	20/04/2023	Yes	No