ISRCTN53778569 https://doi.org/10.1186/ISRCTN53778569

Laboratory parameters in the elderly

Submission date
23/05/2015

Recruitment status
No longer recruiting

Registration date
27/05/2015

Overall study status
Ongoing

Last Edited
18/05/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Laboratory tests are essential to diagnose issues and make treatment decisions. Interpretation of individual results relies on accurate reference intervals and decision limits. A lot of resources are spent on elderly patients but we know very little about accurate reference intervals. The SENIORLAB study aims to address this gap of knowledge by investigating a large variety of laboratory parameters in clinical chemistry, haematology and immunology.

Who can participate?
Senior individuals aged 60 or above, residing in Switzerland and describing themselves as healthy.

What does the study involve?
This is an observational study which involves a visit to the study centre. There will be basic measurements (blood pressure, weight and height) and a fasting blood test. Then participants will be periodically contacted every 3 to 5 years to evaluate their health status.

What are the possible benefits and risks of participating?
Participants receive a selection of results from laboratory tests relevant for healthy seniors (such as glucose, HbA1c, and creatinine). The risk of participation can be considered to be very low and relates to the risk of phlebotomy of a peripheral vein, usually in the cubital region.

Where is the study run from?
Labormedizinisches Zentrum Dr. Risch in Liebefeld (Switzerland)

When is the study starting and how long is it expected to run for?
January 2007 to December 2025

Who is funding the study?
INOVA Foundation (Liechtenstein)

Who is the main contact?
1. Dr Martin Risch (martin.risch@ksgr.ch)
2. Dr Lorenz Risch (lorenz.risch@risch.ch)

Study website
http://www.seniorlabor.ch

Contact information

Type(s)
Scientific

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Public

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3097

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

SENIORLAB: a prospective observational study investigating laboratory parameters and their reference intervals in the elderly

Acronym
SENIORLAB

Study objectives
In clinical practice, laboratory results are very often important when it comes to make diagnostic, therapeutic and prognostic decisions. Interpretation of individual results relies on accurate reference intervals and decision limits. Despite a considerable amount of resources in clinical medicine spent on elderly patients, accurate reference intervals for the elderly are only rarely available. The SENIORLAB study was set out to address this gap of knowledge determining reference intervals in the elderly by investigating a large variety of laboratory parameters in clinical chemistry, hematology, and immunology.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Bern (Kantonale Ethikkommission Bern; KEK), 05/01/2009 & 29/07/2013 (amendment), ref: 166/08

Study design
Single-center observational trial

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
http://seniorlabor.ch/index.php?TPL=10062

Health condition(s) or problem(s) studied
Subjectively healthy elderly persons aged 60 and over

Interventions
An extensive baseline evaluation is undertaken in the study participants. The participants are followed up for quality of life, morbidity and mortality.

Intervention Type
Other

Primary outcome measure

Evaluation of robust reference intervals

Secondary outcome measures
1. Associations between different parameters
2. Diagnostic characteristics of parameters to diagnose different circumstances
3. Prevalence of occult disease in subjectively healthy individuals
4. Risk factors for outcomes

Overall study start date
01/01/2007

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Aged 60 or older
2. Resident in Switzerland
3. Subjective perception of being healthy
4. Fasting state when going for baseline examination

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
1500

Key exclusion criteria
1. Known diabetes mellitus
2. Known thyroid disease
3. Current glucocorticoid use
4. Active neoplastic disease during the past 5 years
5. Consumption of more than 5 pharmacologically active substances (polypharmacy)
6. Hospitalisation during the past 4 weeks

Date of first enrolment
28/05/2009

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Switzerland

Study participating centre
Labormedizinisches Zentrum Dr. Risch
Waldeggstrasse 37
Liebefeld
Switzerland
3097

Sponsor information

Organisation
Labormedizinisches Zentrum Dr. Risch

Sponsor details
Waldeggstrasse 37
Liebefeld
Switzerland
3097

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/030f5x630

Funder(s)

Funder type
Research organisation

Funder Name
INOVA Research Foundation (Forschungs- und Förderstiftung INOVA) Principality of Liechtenstein

Results and Publications

Publication and dissemination plan

Study results are disseminated as original reports in peer-reviewed scientific journals, systematic reviews, as well as contributions to scientific meetings, as follows:
1. Publications of cross-sectional analyses are ongoing since 2012
2. The method paper of the prospective study will be submitted in June 2015
3. Publication of reference intervals will be continuously submitted starting from the second half 2015
4. Longitudinal analyses will be continuously published beginning 2017

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/01/2017		Yes	No
Results article	results	15/05/2018		Yes	No
Results article	8 year follow up	17/05/2023	18/05/2023	Yes	No