

Pilot study of carbohydrate sulfotransferase 7 diagnostic utility in non-small cell lung carcinoma

Submission date 28/09/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/10/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. It usually grows and spreads more slowly than small cell lung cancer. Non-invasive (harmless) yet reliable tests are needed to tell NSCLC apart from other lung diseases that have similar symptoms. Carbohydrate sulfotransferase 7 (CHST7) is a substance that is involved in the development of several different cancers including NSCLC. The aim of this study is find out whether the levels of CHST7 in the blood can be used to tell apart NSCLC from other lung diseases with similar symptoms.

Who can participate?

Patients age over 18 with suspected lung cancer

What does the study involve?

During the routine diagnostic tests for suspected lung cancer, the participants' CHST7 levels are measured along with other blood substances, including routinely used tumor markers. The results are analysed to work out whether CHST7 levels can be used as a way to diagnose NSCLC.

What are the possible benefits and risks of participating?

There are no direct benefits of participation. Participants must provide a routine blood sample; there are no additional risks.

Where is the study run from?

1. Osijek University Hospital (Croatia)
2. Clinical Hospital Center Zagreb (Croatia)

When is the study starting and how long is it expected to run for?

July 2012 to December 2015

Who is funding the study?

1. Osijek University Hospital (Croatia)
2. Našice General Hospital (Croatia)

Who is the main contact?
Dr Zeljko Debeljak

Contact information

Type(s)
Public

Contact name
Dr Zeljko Debeljak

ORCID ID
<http://orcid.org/0000-0002-1789-5387>

Contact details
J. Huttlera 4
Osijek
Croatia
31 000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Carbohydrate sulfotransferase 7 in non-small cell lung carcinoma: a clinical pilot diagnostic accuracy study of the biomarker candidate

Study objectives
Serum carbohydrate sulfotransferase 7 (CHST7) concentration may improve the non-invasive differentiation of non-small cell lung carcinoma (NSCLC) from the pulmonary diseases presenting with similar clinical manifestations including non-malignant inflammations and other malignancies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of Osijek University Hospital, 15/12/2011
2. Ethics Committee of Clinical Hospital Center Zagreb, 04/07/2012

Study design

Two-center case-control diagnostic accuracy study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Non-small cell lung carcinoma

Interventions

Patients are recruited consecutively during the routine diagnostic work up for suspected lung carcinoma. CHST7 concentration is determined along with other serum parameters, including routinely used tumor markers. Its diagnostic performance as a NSCLC biomarker candidate is evaluated during a period of two and a half years.

The CHST7 values of each participant are compared with the appropriate cut off values (index test). According to the comparison participants are classified either to the NSCLC group or to the control group. These classification results are compared with the 'gold standard' i.e. histological or cytological diagnosis (reference standard test).

Intervention Type

Other

Primary outcome measure

The diagnostic utility of CHST7 in NSCLC, evaluated using area under the curve (AUC) and other statistical measures coming from receiver-operation-characteristic analysis

Secondary outcome measures

Evaluation of multivariate performance conducted using crossvalidation accuracy

Overall study start date

01/07/2012

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Age > 18 years
2. Suspected pulmonary malignant disease accompanied with clinical and laboratory signs of inflammation
3. Therapy-naïve

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

150

Key exclusion criteria

1. Participant refused to participate
2. Insufficient or unavailable diagnostic information

Date of first enrolment

04/07/2012

Date of final enrolment

30/04/2015

Locations**Countries of recruitment**

Croatia

Study participating centre

Osijek University Hospital

Osijek

Croatia

31 000

Study participating centre

Clinical Hospital Center Zagreb

Zagreb

Croatia

10 000

Sponsor information

Organisation

Osijek University Hospital

Sponsor details

J. Huttlera 4

Osijek

Croatia

31 000

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Osijek

Funder Name

Našice General Hospital

Results and Publications

Publication and dissemination plan

Results will be disseminated in a form of scientific publication by the end of 2017.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are available from Zeljko Debeljak on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/07/2018		Yes	No