

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

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

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**Contact details**  
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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Diagnostic

**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(s)**

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

**Key secondary outcome(s)**

Evaluation of multivariate performance conducted using crossvalidation accuracy

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

**Funder(s)****Funder type**

Hospital/treatment centre

## Funder Name

University Hospital Osijek

## Funder Name

Našice General Hospital

# Results and Publications

## 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?
<a href="#">Results article</a>	results	26/07/2018		Yes	No