

# Telmisartan for high blood pressure

<b>Submission date</b> 07/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/03/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/03/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many people around the globe suffer from hypertension (high blood pressure). In fact, hypertension is one of the leading causes of illness and death in the world. Moreover, hypertension increases the risk of acute cardiovascular events such as stroke or myocardial infarction (heart attack). One of the main ways to control hypertension is medication. One such medication is telmisartan, which was extensively studied in clinical trials. Nevertheless, clinical trials involve certain groups of patients while the physician was under thorough control of telmisartan use. For that reason, the researchers aim to study telmisartan use in the routine practice of physicians to evaluate its effectiveness against hypertension in real-world conditions.

### Who could participate?

Adults aged over 18 who have high blood pressure and have been prescribed telmisartan alone or in combination with hydrochlorothiazide/amlodipine before enrollment.

### What did the study involve?

Patients are enrolled in the study when the physician decides to prescribe telmisartan or telmisartan with hydrochlorothiazide or telmisartan in combination with amlodipine. Participation in the study does not influence the investigator's decision on treatment choice. After the start of the treatment, patients measure their blood pressure daily and complete diaries. Moreover, data on any adverse events are also collected in order to evaluate the safety of the treatments. Patients complete the diaries across a 12-week period that allows the investigators to monitor blood pressure changes in different circumstances.

### What are the possible benefits and risks of participating?

Participants do not receive a direct benefit from this study as they are receiving treatment as usual. Risks include adverse events that could develop during the study participation.

### Where is the study run from?

Myasnikov's Scientific Research Institute (Russia)

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

November 2017 to April 2019

Who is funding the study?  
Dr. Reddy's Laboratories LLC (Russia)

Who is the main contact?  
Olga D. Ostroumova  
ostroumova.olga@mail.ru

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
DRL\_RUS/PMS/2017/TEL

## Study information

**Scientific Title**  
Telmisartan for the INitiation and maintenance of Antihypertensive treatment: a cross-sectional pharmacoepidemiology and prospective observational study in Russia

**Acronym**  
TAINA

**Study objectives**  
Data from 2,000 individuals who start their drug therapy for arterial hypertension by taking telmisartan or telmisartan H in the therapeutically recommended dose range for 12 weeks will be used to examine the real-world effectiveness and safety of telmisartan and telmisartan H, especially taking into account that current guidelines reconfirm that diuretics, beta-blockers, calcium antagonists, angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers

are all suitable for the initiation and maintenance of antihypertensive treatment, either as monotherapy or in some combinations.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 15/12/2017, Independent interdisciplinary ethical committee (125468, Leningrandsky prospect, 51, Moscow, Russian Federation; +7 (0)9153463030; beresneva.sofia@gmail.com), ref: #20

### **Study design**

Cross-sectional observational prospective multicenter study

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Arterial hypertension

### **Interventions**

Data from 2,000 individuals who start their drug therapy for arterial hypertension by taking telmisartan or telmisartan H in the therapeutically recommended dose range for 12 weeks will be used to examine the effectiveness and safety of telmisartan and telmisartan H as monotherapy or in combination with hydrochlorothiazide/amlodipine in a real-world setting.

Patients are followed-up for 12 weeks after enrollment. During the course of the study data on self-measured blood pressure is obtained by physicians from patients. Additionally, patients fill in EQ-5D quality of life forms, and data on symptoms of hypertension and adverse events are collected.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Telmisartan, hydrochlorothiazide, amlodipine

### **Primary outcome(s)**

1. Demographic, lifestyle and clinical characteristics:

1.1. BMI kg/m<sup>2</sup> data obtained from source documents at Visit 1

1.2. Status of smoking measured using medical history data in source documents and information obtained from the patient at Visit 1

1.3. Alcohol consumption measured using medical history data in source documents and information obtained from the patient at Visit 1

1.4. Sedentary lifestyle measured using medical information obtained from the patient at Visit 1

- 1.5. Cardiovascular risk measured using SCORE assessment at Visit 1
2. Patient self-measurement of blood pressure using home blood pressure monitoring (HBPM) from baseline to endpoint
3. Office blood pressure measurement by medical personnel from baseline to endpoint

### **Key secondary outcome(s)**

1. Tolerability of the therapy measured as the number of patients with adverse reactions and the incidence of different adverse reactions at 12 weeks
2. Course of hypertension-induced renal damage by assessing the following after 12 weeks of treatment:
  - 2.1. Creatinine blood level
  - 2.2. Estimated glomerular filtration rate (eGFR)
  - 2.3. Urinary excretion of albumin
3. Rate (%) of adherence to the initial treatment measured using patient self-report at 12 weeks
4. In the subpopulation reporting headache at baseline, headache symptoms measured using the headache inventory at baseline and 12 weeks
5. Number of patients with controlled AH (continuous maintenance of target blood pressure according to 2013 ESC guidelines) at 12 weeks
6. Patients' satisfaction with their treatment as measured by patient diary at baseline and the end of 12 weeks of telmisartan treatment
7. Health-related quality of life (HRQOL) measured at baseline and 12 weeks by:
  - 7.1. SF-36 Health Survey summary
  - 7.2. Likert scale score assessing the changes in patient's daily life

### **Completion date**

15/04/2019

## **Eligibility**

### **Key inclusion criteria**

1. ICF signed prior to enrollment
2. Hypertension diagnosis verified
3. Office SBP >140 mmHg and/or office DBP >90 mmHg
4. Absence or inefficacy of antihypertensive treatment prior to enrollment
5. Decision of telmisartan prescription as monotherapy or in combination with hydrochlorothiazide/amlodipine was taken by the physician prior to enrollment

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

1999

### **Key exclusion criteria**

1. Telmisartan treatment during 90 days prior to enrollment
2. Malignant hypertension
3. Secondary hypertension
4. Refuse to monitor BP by patient
5. Pregnancy and lactation period
6. Any condition that could alter patient safety or protocol procedures during the course of study
7. Any condition that by physician's decision could stop from patient enrollment
8. Hypersensitivity, significant ADRs or contraindications for telmisartan treatment
9. Refusal to follow the physician's instructions

### **Date of first enrolment**

26/12/2017

### **Date of final enrolment**

27/03/2019

## **Locations**

### **Countries of recruitment**

Russian Federation

### **Study participating centre**

#### **Myasnikov's Scientific Research Institute**

3-ya Cherepkovskaya st., 15a

Moscow

Russian Federation

121552

### **Study participating centre**

#### **City clinical hospital 29 for N.E. Bauman**

Budenny av., 37/1

Moscow

Russian Federation

105275

### **Study participating centre**

#### **City clinical hospital 29 for M.E. Jadkevitch**

Mozhayskoye highway, 14

Moscow

Russian Federation

121374

**Study participating centre**

**Moscow county scientific research institute for M.F. Vladimirsky**

Schepkina st. 61/2

Moscow

Russian Federation

129110

**Study participating centre**

**National scientific research institute of preventive medicine**

Petroverigskiy al., 10

Moscow

Russian Federation

101990

**Study participating centre**

**Polyclinic #3**

Grokholskiy al, 31

Moscow

Russian Federation

129090

**Study participating centre**

**City clinical hospital #7**

Marshala Chuikova st., 54

Kazan

Russian Federation

420103

**Study participating centre**

**Department of hospital therapy of State Budgetary Educational Institution of Higher Education  
"Nizhny Novgorod State Medical Academy" based at "N.A. Semashko County Clinical Hospital"**

Rodionova st., 190

Nizhny Novgorod

Russian Federation

603093

**Study participating centre**

**Department of internal diseases of State Budgetary Educational Institution of Higher Education  
"Nizhny Novgorod State Medical Academy" based at "City Clinical Hospital #38"**

Chernyshevskogo st., 22  
Nizhny Novgorod  
Russian Federation  
603000

**Study participating centre**

**Federal State Budgetary Healthcare Institution "Samara County Clinical Cardiological Dispensary"**  
Aerodromnaya st., 43  
Samara  
Russian Federation  
443070

**Study participating centre**

**State Healthcare Institution "Saratov City Polyclinic #2"**  
Moskovskaya st., 137/149  
Saratov  
Russian Federation  
410012

**Study participating centre**

**Federal State Budgetary Educational Institution of Higher Education "Bashkirian State Medical University"**  
Lenina st., 3  
Ufa  
Russian Federation  
450000

**Study participating centre**

**City Clinical Hospital #1**  
Vorovskogo st., 16  
Chelyabinsk  
Russian Federation  
454092

**Study participating centre**

**LLC "Medical Union "New Hospital"**  
Zavodskaya st., 29 b.3  
Ekaterinburg  
Russian Federation  
620109

**Study participating centre**

**Federal State Budgetary Educational Institution of Higher Education "Tyumen State Medical University"**

Odesskaya st., 54

Tyumen

Russian Federation

625023

**Study participating centre**

**District Budgetary Healthcare Institution "Krasnoyarsk District Clinical Hospital"**

Partizana Zheleznyaka st., 3a

Krasnoyarsk

Russian Federation

660022

**Study participating centre**

**Federal State Budgetary Educational Institution of Higher Education "Pacific State Medical University"**

Ostryakova st., 2

Vladivostok

Russian Federation

690002

**Study participating centre**

**State Budgetary Healthcare Institution "Irkutsk County Clinical Hospital"**

Carla Marksa st., 29

Irkutsk

Russian Federation

664003

**Study participating centre**

**Federal State Budgetary Scientific Institution "Scientific Research Institute for Complex Cardiovascular Diseases Problems"**

Sosnoviy bor, 6

Kemerovo

Russian Federation

650000

**Study participating centre**

**Federal State Budgetary Educational Institution of Higher Education "Krasnoyarsk State Medical University of V.F. Voyno-Yasenetskiy"**

Partizana Zheleznyaka st., 1  
Krasnoyarsk  
Russian Federation  
660022

**Study participating centre**

**Polyclinic #9 at State Autonomous Healthcare Institution "City Clinical Hospital #1"**

Khitarova st., 32  
Novokuznetsk  
Russian Federation  
654027

**Study participating centre**

**State Autonomous Healthcare Institution "City Clinical Hospital #1"**

Bardina st., 28  
Novokuznetsk  
Russian Federation  
654057

**Study participating centre**

**Federal State Budgetary Healthcare Institution "Novosibirsk County Clinical Cardiological Dispensary"**

Zaleskogo st., 6/8  
Novosibirsk  
Russian Federation  
630047

**Study participating centre**

**Federal State Budgetary Scientific Institution "Scientific Research Institute of Cardiology"**

Kiyevskaya st., 111a  
Tomsk  
Russian Federation  
634012

**Study participating centre**

**District Budgetary Healthcare Institution "City Polyclinic #3"**

Dikopoltseva st., 34

Khabarovsk  
Russian Federation  
680000

**Study participating centre**

**State Budgetary Healthcare Institution "Novosibirsk State County Clinical Hospital"**

Nemirovicha-Danchenko st., 130  
Novosibirsk  
Russian Federation  
630087

**Study participating centre**

**State Budgetary Healthcare Institution Scientific Research Institute "District Clinical Hospital"**

May 1st st., 167  
Krasnodar  
Russian Federation  
350086

**Study participating centre**

**Municipal Budgetary Healthcare Institution "City Emergency Care Hospital of Rostov-na-Donu"**

Bodraya st., 88/35  
Rostov-na-Donu  
Russian Federation  
344068

**Study participating centre**

**State Budgetary Healthcare Institution of Republic of Crimea "Republican Clinical Hospital for N. A. Semashko"**

Kiyevskaya st., 69  
Simpferopol  
Russian Federation  
295017

**Study participating centre**

**State Budgetary Healthcare Institution of Stavropol District "District Clinical Cardiological Dispensary"**

Prigorodnaya st., 224a  
Stavropol  
Russian Federation  
355026

**Study participating centre**  
**International Medical Centre "Sogaz"**  
Malaya Konushennaya st., 8  
Saint-Petersburg  
Russian Federation  
191186

**Study participating centre**  
**Multibranch Medical Diagnostic Centra "Medsanchast #157"**  
Warshavskaya st., 100  
Saint-Petersbutg  
Russian Federation  
196066

**Study participating centre**  
**Saint-Petersbutg State Budgetary Healthcare Institution "City Diagnostic and Consultation Centre #1"**  
Sikeyros st., 10a  
Saint-Petersburg  
Russian Federation  
194354

**Study participating centre**  
**Budgetary Healthcare Institution "Voronezh county clinical hospital".**  
Moskowsky prospect, 151a  
Voronezh  
Russian Federation  
394066

**Study participating centre**  
**County Budgetary Healthcare Institution "Voronezh City Polyclinic #5"**  
Zapolnaya st., 43a  
Kursk  
Russian Federation  
305000

**Study participating centre**  
**"Therapeutic-diagnostic clinic" LLC**  
2-ya Kiyevskaya st., 11

Smolensk  
Russian Federation  
214018

## Sponsor information

### Organisation

Dr. Reddy's Laboratories (Russia)

## Funder(s)

### Funder type

Industry

### Funder Name

Dr. Reddy's Laboratories LLC

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to terms of an agreement between the investigators and the sponsor.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	07/04/2020	07/12/2020	Yes	No
<a href="#">Protocol file</a>	version v1		15/03/2021	No	No