ISRCTN54936745 https://doi.org/10.1186/ISRCTN54936745

Telmisartan for high blood pressure

Submission date	Recruitment status	[_] Prospectively registered
07/12/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/03/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/03/2021	Circulatory System	

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.

Wha 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
Prof Olga Ostroumova

ORCID ID
http://orcid.org/0000-0002-0795-8225

Contact details
Bolshaya Pirogovskaya st., 2 b. 4
Moscow
Russian Federation
119435
+7 (499) 248 -75-44
ostroumova.olga@mail.ru

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 telsartan or telsartan H in the therapeutically recommended dose range for 12 weeks will be used to examine the real-world effectiveness and safety of telsartan and telsartan 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

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 telsartan or telsartan H in the therapeutically recommended dose range for 12 weeks will be used to examine the effectiveness and safety of telsartan and telsartan 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, hydrochlorthiazide, amlodipine

Primary outcome measure
1. Demographic, lifestyle and clinical characteristics:
1.1. BMI kg/m² 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

Secondary outcome measures
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

Overall study start date
29/11/2017

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

Age group
Adult

Sex
Both

Target number of participants
2,200

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 medicicne
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"
Zalesskogo 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 ClinicalHospital"
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 Crymea "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)

Sponsor details
Ovchinnikovskaya emb., 20 b. 1
Moscow
Russian Federation
115035
+7 (495)783-29-01
Anastasiya.Nasonova@drreddys.com

Sponsor type
Industry

Website
http://www.drreddys.ru/

Funder(s)

Funder type
Industry

Funder Name
Dr. Reddy's Laboratories LLC

Results and Publications

Publication and dissemination plan
Part of the study results are already published in a Russian scientific medical journal and the rest are yet to be published in an international journal.

Intention to publish date
01/01/2021

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?
Results article	results	07/04/2020	07/12/2020	Yes	No
Protocol file	version v1		15/03/2021	No	No