SVERDLOVSK REGIONAL CLINICAL HOSPITAL No. 1
State-Financed Health Institution
Sverdlovsk region
2017

ABP 051

Зарегистрирован
в качестве **медицинского изделия в РФ и ЕС**

Регистрационное удостоверение
РЗН 2016/3776 от 31.03.2016.
EC Certificate № 1942/MDD от 01.09.2017.

Ministry of Health
of Sverdlovsk region
State-Financed Health Institution
of Sverdlovsk region
"SVERDLOVSK REGIONAL CLINICAL HOSPITAL No. 1"
(SFHI of SR "SRCH No. 1»)
185 Volgogradskaya St., 620102 Yekaterinburg
Tel./fax 351-15-15/240-47-56 e-mail: office@okb1.ru
http://www.okb1.ru
OKPO 01944482, OGRN 1026602329710, INN / KPP 6658081585 / 665801001

APPROVED BY
Chief Doctor of SFHI of SR "SRCH No. 1"

<*Signature*> F. I. Badayev

L.S. <Seal: Ministry of Health of Sverdlovsk region; State-Financed Health Institution of Sverdlovsk region; "Sverdlovsk Regional Clinical Hospital No. 1" (SFHI of SR "SRCH No. 1"); OGRN 1026602329710; OKPO 1026602329710; INN 6658081585>

Clinical data sheet for medical device No. 07082017-01 as of August 7, 2017

1.1 Name of medical device (including the accessories necessary for the use of medical device for the intended purpose) and manufacturer:
Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction according to TC 9444-005-12342964-2015 Manufacturer: "Inferum" Limited Liability Company, Belinskogo St. 86-487, 620026 Yekaterinburg, Russia

1.2 Name of organization leading clinical trials of medical device:
SFHI of SR "Sverdlovsk Regional Clinical Hospital No.1" (further – "SFHI of SR "SRCH No.1"), 185 Volgogradskaya St., 620102 Yekaterinburg, Russia. This study was carried out on the basis of Nephrological Department (Head of Department – A.G. Stolyar, Dr.med.habil.), Rheumatology Department (Head of Department – L.P. Yevstigneeva, Ph.D. (Medicine)) of SFHI of SR "Sverdlovsk Regional Clinical Hospital No.1" (Chief Doctor – F.I. Badayev, Dr. med. habil., honored doctor of the RF)

1.3 Authority for test performance:
License for medical activities: No. ЛО-66-01-004475 as of 19.01.2017, issued by the Ministry of Health of Sverdlovsk region, in perpetuity. "SFHI of SR "SRCH No. 1" is included in the List of medical organizations that lead clinical trials of medical devices as of 20.10.2014.

1.4 Basis for clinical trials:
Appeal for clinical testing as of June 05, 2017

Extract from the minutes of the local Ethics Committee meeting No. 125 as of 05.07.2017

1.5 Period of clinical trials:
From July 05, 2017 till August 07, 2017

1.6 Form of clinical trials:
In-human clinical trials of medical device

1.7 Name of manufacturer, the country of manufacturing in accordance with name and designation of technical and operational documentation:
"Inferum" Limited Liability Company, Belinskogo St. 86-487, 620026 Yekaterinburg, Russia.

1.8 Clinical trial applicant:
"Inferum" Limited Liability Company, Belinskogo St. 86-487, 620026 Yekaterinburg, Russia.
1.9 Clinical trial sponsor:
"Inferum" Limited Liability Company, Belinskogo St. 86-487, 620026 Yekaterinburg, Russia.

1.10 Experts who conducted the tests:
L.G. Karavayeva, staff doctor of SFHI of SR "SRCH No.1"
V.A. Tikhonova, staff doctor of SFHI of SR "SRCH No.1"
A.A. Neganova, coordinating investigator

2. The following documents were provided for clinical trial of the medical device:

No.	Document name
1	Appeal for clinical testing as of June 05, 2017
2	Extract from the minutes of the local Ethics Committee meeting No. 125 as of 05.07.2017
3	Registration certificate for medical device No. РЗН 2016/3776 as of March 31, 2016.
4	Clinical trial protocol in the form of analysis and evaluation of clinical data for medical device No. 2 as of January 22, 2016. "Transcutaneous electrostimulator "ABP" for arterial blood pressure correction according to TC 9444-005-12342964-2015" ("European Medical Center UGMK-Zdorovye" OOO, Yekaterinburg)
5	Patient brochure, patient information sheet and informed consent of the patient (attachment to Patient Information Sheet)
6	Instruction for use INFE 05.01-03.70-01ИП
7	Journal of patients included in the study
8	Patient questionnaire
9	Patient observation card in 2 forms
10	List of adverse reactions (AR)
11	Card for informing about an adverse event caused by the medical device (incident / risk of incident)

3. Results and evaluation of clinical trial results

SFHI of SR "SRCH No. 1", Yekaterinburg, evaluated the results of clinical trials and the analysis of clinical data obtained as a result of the application of "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction according to TC 9444-005-12342964-2015" medical device (further, "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction", "apparatus", "medical device"), manufactured by "Inferum" OOO, Russia. In accordance with the

approved program for evaluation of results of medical device clinical trials as of June 05, 2017 (Appendix 1 to this Act) and with the Clinical Trial Protocol (Appendix 2 to this Act) it was established the following:

3.1 Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction is a mobile, light-weight and compact device that allows you to carry out procedures at any convenient time, anywhere:

— it acts without subcutaneous introduction, has no risk of infection;

— it is painless;

— it has short action time (6 minutes);

— it is applicable in outpatient and home conditions

3.2 Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction was designed for stimulation of reflexogenic zones of the human body in the wrist area using electric current of various frequencies.

3.3 Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction is classified as a physiotherapy device.

The type of medical device in accordance with Nomenclature Classification of Medical Devices approved by the Ministry of Health of the Russian Federation is **181480**.

3.3 Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction has 2a class of potential risk of medical device application in accordance with GOST 31508 and Order of the Ministry of Health of Russia No. 4н as of 06.06.2012.

3.4 Documentation for "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device is presented in full.

3.5 During this study 540 examinations were performed, heart rate and pulse were measured 4,320 times, and blood pressure was measured 4,320 times.

3.6 During the clinical trials operating time of medical device in placebo group was 6 hours, in the main group – 42 hours.

3.7 Application of "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device is indicated at:

- Persistently high arterial blood pressure in patients with essential hypertension – as an additional treatment to comprehensive drug treatment.
- Episodic arterial blood pressure increase under stress situations, weather changes, etc. in patients with labile arterial hypertension.
- Low blood pressure in patients with hypotension – as an additional treatment to comprehensive drug treatment.

Application of "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device is contraindicated in following cases and diseases:

- implanted pacemaker;
- atrial fibrillation;
- individual intolerance to electric current;
- skin lesion in the left wrist zone;
- neoplasms (tumors) of any origin and localization;
- acute febrile conditions of unclear origin;
- acute psychic excitement, alcohol or drug abuse

3.8 Performance characteristics of the medical device correspond to the declared ones; device is easy to use and aesthetically pleasing.

3.9 During the study medical device was disinfected with 3% solution of hydrogen peroxide.

3.10 During the study of "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device no problems were revealed.

3.11 Statistical analysis was carried out using Statistica 6.0 program. All results were represented as arithmetic mean value ± standard deviation (M±б), as well as in percentage.

Statistical processing of data obtained was carried out using nonparametric methods of statistical analysis. Paired Student t-test was used for comparing quantitative characteristics in two samples. Statistically significant differences were determined at $p < 0.05$.

The sample included patients diagnosed with arterial hypertension of different severity (I-III st.) or symptomatic (nephrogenic, vasorenal) hypertension who agreed to participate in study.

36 patients took part in this study: 11 men and 25 women.

There were no age limits, the age of patients was from 20 to 80 years; the average one was 51.2 ± 2.5 years.

36 patients included in study were put in three groups: group No. 1 and group No. 2 were equal – 15 patients in each one and group No. 3 (control "placebo group") included 6 patients.

In group No. 1 were patients who had "mild" arterial hypertension with the following blood pressure range:

— SBP: 145±5.5 mm Hg ÷ 160±4.5 mm Hg;

— DBP: 85±3.5 mm Hg ÷ 100±6.5 mm Hg.

Group No. 2 included patients diagnosed with "moderate" or "significant" hypertension with the following blood pressure range:

— SBP: 165±7.5 mm Hg ÷ 180±5.5 mm Hg;

— DBP: 105±3.5 mm Hg ÷ 110±4.5 mm Hg.

Group No. 3 ("placebo group") included patients with "mild" arterial hypertension (3 patients), "moderate" and "significant" hypertension (3 patients).

Group No. 1 and group No. 2 were treated with "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device in addition to drug therapy.

Group 3 ("placebo group") received only hypotensive drug therapy, application of "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device was performed with switched off electrodes.

As a result of the study of "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device for treatment of patients with arterial hypertension the following results were obtained:

— in group No. 1 (patients with "mild" hypertension) 13 patients (84.3%) showed good effect (persistent decrease and normalization of blood pressure); in 2 patients (15.7%) there was no significant effect;

Table 1

Arterial blood pressure range in Group No. 1

Value	Before treatment	After treatment	Effect
SBP	145.3±11.2*	130.2±9.2*	15.1±3.2
DBP	82.3±2.4	76.3±1.8	6.0±0.7

Note: * - statistically significant difference was obtained ($p<0.05$)

— in group No. 2 (patients with moderate and severe hypertension) good effect (persistent decrease and normalization of blood pressure) was obtained in 10 patients (66.6%); in 5 patients (33.3%) there was no significant effect;

Table 2

Arterial blood pressure range in Group No. 2

Value	Before treatment	After treatment	Effect
SBP	175.3±13.2*	160.2±9.8*	15.1±3.6
DBP	92.7±2.4	86.3±1.8	6.4±0.8

Note: * - statistically significant difference was obtained ($p<0.05$)

— in group No. 3 patients (control "placebo group") good effect (persistent decrease and normalization of blood pressure) was obtained in 1 patient (16.7%), 5 patients (83.3%) showed no significant effect.

As a result of study of "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device for treatment of patients with arterial hypertension we can see that the application of this device can shorten the time of blood pressure normalization, can reduce antihypertensive drugs dose in several patients, and can even stop using drug therapy in patients with "mild" or "situational" arterial hypertension.

Application of medical device is safe; no side effects have been reported.

No therapeutic effect was observed in "placebo group".

3.12 Application of "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction" medical device can be recommended both as special treatment and as addition to antihypertensive drug therapy.

3.13 The results of study are reliable because there was a control group; groups of included patients were randomized by age and severity of hypertension.

Conclusion: "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction according to TC 9444-005-12342964-2015" medical device MEETS the requirements of

regulatory documentation, technical and operational documentation of the manufacturer.

Appendices:

1. Program of clinical trials for "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction according to TC 9444-005-12342964-2015" medical device as of June 05, 2017;
2. Protocol of clinical trials for "Transcutaneous electrostimulator ABP-051 for arterial blood pressure correction according to TC 9444-005-12342964-2015" medical device as of August 07, 2017;
3. Registration certificate for medical device No. РЗН 2016/3776 as of March 31, 2016;
4. Extract from the minutes of the local Ethics Committee Meeting No. 125 as of 05.07.2017.

Researchers:

Staff doctor of SFHI of SR "SRCH No.1"	<*Signature*>	L.G. Karavayeva
Staff doctor of SFHI of SR "SRCH No.1"	<*Signature*>	V.A. Tikhonova
Coordinating investigator:	<*Signature*>	A.A. Neganova

Данный перевод с русского языка на английский язык выполнен мной, переводчиком Чижиковой Валентиной Павловной. Верность перевода подтверждаю.

Чижикова Валентина Павловна

Российская Федерация

Город Екатеринбург Свердловской области .
Двадцатого ноября две тысячи семнадцатого года.

Я, Пономарева Фанья Равельевна, временно исполняющая обязанности нотариуса города Екатеринбурга Филипповой Ольги Владимировны, свидетельствую подлинность подписи переводчика Чижиковой Валентины Павловны.

Подпись сделана в моем присутствии.

Личность подписавшей документ установлена.

Зарегистрировано в реестре: № **7-5967.**

Взыскано государственной пошлины (по тарифу): 100 руб. 00 коп.

Уплачено за оказание услуг правового и технического характера: 480 руб. 00 коп.

Ф.Р. Пономарева

Лицензия № 241 выдана 27.12.2001 года Главным управлением Министерства юстиции Российской Федерации по Свердловской области; Адрес нотариальной конторы: г. Екатеринбург, ул. 8 Марта, д. 7, тел. 371-89-72, 3-724-725.

Компьютерная система "Экспресс"