Clinical Trial Report on DJT-4T Diabetes Treatment Instrument (Final)

Product:
HUA HAN ZHEN SHEN® Diabetes Treatment Instrument

Model:
DJT-4T

Category:
Clinical Trial Application

Clinical Trial Applicants:
Beijing Golden Huahan New Technology Co.,Ltd.
Hanzhong Golden Huahan Medical Equipment Co.Ltd.

Clinical Trial Operator:
The First Affiliated Hospital of Tianjin Univeristy of TCM
The Second Affiliated Hospital of Tianjin University of TCM

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Date:
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1. Preface

A. Background

Beijing Golden Huahan New Technology Co., Ltd. is a large-scale private enterprise specialized in R & D and production of medical equipment. Hanzhong Golden Huahan Medical Equipment Co., Ltd. is one of the production bases. Series of HUA HAN ZHEN SHEN® diagnosis and treatment instrument has been achieving good social and economic benefits ever since it put into the market.

The instrument under clinical trial is DJT-4T, one of product series of HUA HAN ZHEN SHEN® diagnosis and treatment instruments, which is in accordance with YZB/Shaan0110-2008 Registered Product Standards, and has won the latest self-testing report issued by its subordinate production enterprise as well as the qualified registration inspection reports issued by Tianjin Product Quality Inspection centre and Guangdong Medical Devices Quality Surveillance and Test Institute.

B. Product Principle

Traditional Chinese Medicine hast it, all human body organs have corresponding acupuncture point(abbreviated as acupoint) on the projecting parts such as ear, hand and foot etc. When there are certain pathological changes in organs, the biological electric current of the corresponding acupoint on ears will vary accordingly. When you treat diseases with HUA HAN ZHEN SHEN® DJT-4T diabetes treatment Instrument, Diversified frequency pulse waves from multiple sources of information emitted by Intermittent control circuit will be transferred as electric signals of pulse waves under output intensity adjustment and buffer enlargement and transmitted via output terminals, stimulate the acupoints on ears and other parts of human body through diagnosis and treatment wire, dredge the meridians and collaterals, regulate Qi and Blood, so as to achieve the purpose of holographic electronic acupuncture treatment.

Approved by the studies on modern pathology and large number of clinical cases, under the electronic acupoint stimulation, the physiological and biochemical changes in the body of diabetics are mainly as follows:

a. Electronic acupoints stimulation helps to elevate insulin level, so do insulin targeted cells reception function, further strengthen functions of glucose synthesis, metabolism, Oxidative glycolysis and organization absorption, thus achieving the purpose of decreasing the level of blood glucose.

b. T3 and T4 values of diabetics drop after electronic acupoints stimulation, which indicates the contents of thyroxine has decreased, thus reducing the impact on glucose metabolism and is conducive to lower blood glucose.

c. Electronic acupoints stimulation of the diabetics could decrease the level of abnormal indicators of hemorrheology such as whole blood viscosity and plasma viscosity and so on. This is of great significance to improve microcirculation barriers, preventing thrombosis, reducing chronic complications of diabetes.

d. Electronic acupoints stimulation helps to adjust central nerve systems which affect the secretions of insulin, thyroxine and adrenaline, so as to correct glucose metabolism disorders.

In addition, electronic acupoints stimulation has a significant impact on central nerve systems which could make the feedback paths of blood glucose adjustment more perfect and sensitive, thus body will have a benign self-adjustment mechanism for blood glucose.

HUA HAN ZHEN SHEN® Diabetes Treatment Instrument (Model No.: DJT-4T) adjusts patents' blood glucose double-way by accurate electronic acupoint stimulation, gradually corrects pathological changes of human body, so as to achieve the treatment purpose.

2. General Clinical Information (Inclusion Criteria)

Total 61 cases are screened for this clinical trial, among which, 31 diabetics are from endocrinology division of First Affiliated Hospital of Tianjin University of TCM, and the other 30 cases are from Second Affiliated Hospital of Tianjin University of TCM.

A. Screening Criteria

a. Basic conditions:

a). Well informed of this trial conditions, volunteers with Information consent form signed

b). Type-1 & Type-2 Diabetics (according to WHO standard, 1999) with fasting blood glucose values between 7.21~12.0mmol/L for twice

c). 18~70 year old, men or women

d). No participation in any other drug experiments in the last 3 months

b. Selection standards:

a). Newly diagnosed diabetics with hyperglycemia, no oral hypoglycemic drugs taken or insulin injection experiences

b). Can not control blood sugar well even taking hypoglycemic drug or insulin, with slight diabetes complications, currently with no medication and insulin

c). Can not control blood glucose level well even taking hypoglycemic drug or insulin, currently reduce the dosage of hypoglycemic drug or insulin, with typical diabetes complications

B. Exclusion standards

a. Patients can not meet the conditions and standards mentioned above

b. Pregnant and lactating women.

c. Patients embeded in electronic devices such as heart pacemaker and cerebral electrodes

d. Patients with diseases such as severe cardiopathy, hypertension, fractures, hemorrhage

C. Elimination standards

Patients with adverse events occurred, fail to continue the trial.

a. Patients with Inadequate therapeutic period, increase the dosage of medicine without physician's consent that influence the judgment of treatment effects

b. Patients who can not meet inclusion standards or meet exclusion standards

c. Patients who has not been treated by HUA HAN ZHEN SHEN® or has no follow-up visit records after treatment

d. Others

3. Methods

A. Treatment Methods:

choose electronic auricular module electrode, assisted with self-adhesive electrode pad, insole electrode or hand palm electrode to stimulate acupoints.

B. Treatment Time:

1~2 times per day at fixed time, 30~40 minutes each time for 30 consecutive days, do follow up visits 30 days after treatment.

4. Clinical Evaluation Criteria

A. Effectiveness Indicators

a. Fasting Blood Glucose (0, 5th, 10th, 20th, 30th day)

b. Glycosylated hemoglobin (zero, sixtieth day)

c. Symptoms and physical signs(zero, thirtieth day)

B. Safety Indicators

a. Adverse reactions that may occur

b. Vital signs

5. Statistical methods and evaluation methods adopted

A. Measurement data, number of cases, average value, standard deviation, maximum and minimum value descriptions; Enumeration data, number of cases, constituent descriptions.

B. Comparison of therapeutic results before and after treatment, paired T- test.

6. Clinical trial result

A. Comparative analysis

61 cases adopted from 62 planned cases sourced from endocrinology division of First Affiliated Hospital of Tianjin University of TCM and Second Affiliated Hospital of Tianjin University of TCM. And all patients have finished the period of treatment as requested in trial program.

a. Demographic information

Chart 1. Gender

Item	N	Male	Female
Gender	61	24(39.34%)	37(60.66%)

Charter 2-1. Age

Item	N	Mean	Std	Min	Max
Age(s)	61	57.705	8.570	24.000	70.000

Chart 2-2. Age Subsection

Item	N	18~40	41~60	61~70
Age Subsection	61	1(1.639%)	35(57.377%)	28(45.901%)

Chart 3. General Physical Examination Items

Items	N	Mean	Std	Min	Max
Height	61	165.9016	5.4150	151.000	174.000

Items	N	Mean	Std	Min	Max
Weight	61	66.7708	10.2945	48.000	95.000
Systolic B.P	61	135.9016	15.3161	100.000	170.000
Diastolic B.P.	61	83.1146	9.4061	65.000	95.000
Breath	61	18.6068	1.3940	16.000	23.000
Pulse	61	78.6068	6.6478	55.000	100.000

b. Patients' conditions before treatment

Chart 4. Course of disease(years)

Item	N	Mean	Std	Min	Max
Course of disease	61	6.8195	5.1622	1.000	20.000

Chart 5. Disease Classification

Item	N	Type 1	Type 2
Disease classifications	61	1(1.639%)	60(98.361%)

Chart 6. Main Diabetes Complications

Complications	Cardiovascular disease	Nephropathy	Retinopathy
No. of Cases	47(77.049%)	22(36.066%)	13(21.311%)
Complications	Nervous System	Ketotic coma	Concurrent infection
No. of Cases	57(93.443%)	4(6.557%)	7(11.475%)
Complications	Skin, muscle and joint lesions	Others	
No. of Cases	2(3.279%)	0(0%)	

c. Symptoms before treatment

Chart 7. Pre-treatment Symptoms

Symptoms	Diuresis	Polydipsia	Polyphagia	Hypodynamia	Emaciation

No. of cases	19(31.148%)	36(59.016%)	18(29.508%)	40(65.574%)	9(14.754%)

d. Laboratory test before treatment

Chart 8. Conditions of Blood Glucose and Glycosylated Hemoglobin

Item	N	Mean	Std	Min	Max
Fasting blood glucose	61	10.1397	2.4848	7.400	19.700
Postprandial blood glucose	31	13.932	4.398	9.100	25.800
Glycosylated hemoglobin	61	7.8867	1.3552	5.800	11.800

B. Analysis on Effects of Clinical trial

a. Comparison of therapeutic results of fasting blood glucose

Chart 9-1. Condition of Fasting Blood Glucose at Different imes

Times	N	Mean	Std	Min	Max
Pre-treatment	61	10.140	2.485	7.4	19.7
fifth day of treatment	61	9.441	2.217	5.1	17.8
tenth day of treatment	61	8.736	1.577	5.6	14.1
twentieth day of treatment	61	8.198	1.459	5.4	12.7
thirtieth day of treatment	61	8.039	1.345	5.8	12.3

Chart 9-2. Comparison of Changes of fasting blood glucose at various times

Times	N	Mean	Std	Min	Max	T	P
Pretreatment-fifth day of treatment	61	0.698	0.901	-0.300	6.000	6.0523	0.000
Pretreatment-tenth day of treatment	61	1.403	2.021	-0.900	10.000	5.4242	0.000
Pretreatment-twentieth day of treatment	61	1.941	1.962	-0.800	9.900	7.7252	0.000
Pretreatment-thirtieth day of treatment	61	2.100	2.011	0.300	10.800	8.1568	0.000

b. Comparison of therapeutic effects on glycosylated hemoglobin

Chart 10. Comparison of effects of glycosylated hemoglobin

Items	N	Mean	Std	Min	Max	T	P
Pre-treatment	61	7.887	1.355	5.800	11.800	-	-
30 days after treatment	61	7.198	1.495	4.800	12.500	-	-
Pretreatment-30 days after treatment	61	0.687	0.561	0.200	1.600	9.5512	0.000

c. Clinical Symptoms and Changes of Physical Signs after Treatment

Chart 11. Change of symptom and physical signs

Items	N	Disappear	Improved	No change	Effective rate (%)
Polyuria	19	2(10.526%)	14(73.684%)	3(15.789%)	84.211
Polydipsia	36	1(2.778%)	35(97.222%)	0(0%)	100
Polyphagia	18	5(27.778%)	12(66.667%)	1(5.556%)	94.444
Hypodynamia	40	3(7.500%)	33(82.500%)	4(10.000%)	90.000
Become thin	9	0(0%)	0(0%)	9(100%)	0

7. Safety Analysis

A. Adverse Events:
No adverse events happened during clinical trial

B. Vital Signs:
Normal, no significant changes of vital signs before and after treatment

8. Analysis on clinical trial effect and safety

According to the clinical trial plan, total 61 cases valid with 0 case shed off and eliminated, all participants have signed informed consent forms. Among which, 24 male cases, 37 female cases, 1 case type 1 diabetics, 60 cases type 2, with at least 1 year disease course, at most 20 years.

Statistics show that there are significant differences on the fifth, tenth, twentieth and thirtieth day with fasting blood glucose value and glycosylated hemoglobin decreased gradually compared with the levels before treatment, moreover, the diabetic complications have also improved a lot.

61 diabetics accepted treatment and observation in accordance with the requirements of the program, with no side effects occurred, vital signs such as systolic blood pressure, diastolic blood pressure, breath and pulse all in the normal range before and after treatment.

9. Conclusions

HUA HAN ZHEN SHEN® diabetes treatment instrument DJT-4T helps to decrease fasting blood glucose and glycosylated hemoglobin of diabetics, with no side-effects happened in the process of the trial.

10. Indications & Scope, Contraindications and Precautions

A. Indications & Scope: diabetes and its complications.
B. Contraindications and Precautions:
a. Don't store in humid place
b. Patients who are using electronic apparatus such as build-in heart pacemaker and brain electrodes
c. Pregnant and lactating women

11. Problems and recommendations for improvement

None

12. Persons who participated the clinical trial

See in the attached reports

13. Approval by Panels of Clinical Trial Management Divisions

Approved

The First Affiliated Hospital of Tianjin University of TCM

Clinical Trial Organization (Seal)
Date: May19th, 2009

Approved

The Second Affiliated Hospital of Tianjin University of TCM

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