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Clinical Trial Protocol of the RTM-01 Microwave Radiometer Developed by RES Ltd.

Over the period from January 21 to March 31, 1998, at the Oncologic Department of Moscow Branch № 1 of the Mammalogy Dispensary clinical trial of the RTM-01 microwave radiometer, developed by RES Ltd., was carried out.

The Purpose and Methods of the Clinical Trial

The purpose of the clinical trial is to estimate the ability to use the RTM-01 microwave radiometer in medical practice.

To carry out the clinical trial the RTM-01 0021 microwave radiometer was chosen. It consists of:

sensor to measure the temperature of the internal organs with an antenna for detecting natural electromagnetic radiation (RS block)

skin temperature sensor

processing unit (DP block)

The RTM-01 is a modulated null-radiometer with a slipping circuit for compensating the reflection between the biological object and the antenna.

The scheme of the device is protected by the Russia patent 2082118.

The principle of device operation bases on measuring the intensity of natural electromagnetic radiation from a patient's internal tissues at microwave frequencies. The intensity of the radiation is proportional to the temperature of tissues according to physics laws (Plank's formula).

The basic medical and technical parameters of the radiometer are the following:

Table 1.

Thermal abnormality is detected at the depth of	3 - 5 cm
Accuracy of the temperature measurement	± 0,2° C
Time of measuring one point	15 sec
Antenna diameter	39 mm
Power consumption from 220 V 50Hz network	15 Watt
Weight of the basic set	3 kg
Dimensions	
DP block	260x230x70 mm
RS block	200x60x30 mm

Temperature data are displayed as a three-digit number on the panel with discreteness of 0,1° C. Radiometer may be connected with a PC. Also software for inputting and storing data of patients, brief anamnesis, visualization and processing the results of measurements was supplied.

The radiometer may be used in the following modes:

- autonomous mode (in this case manipulations with device are carried out by a doctor or a nurse, the data received may be input into computer manually);

- computer based mode (the input of measurement data is made automatically, the visualization and measurement data are processed after the examination of a patient is complete).

Women were tested on 6 to 9 days from the first day of their period of menstruation.

The measurement scheme of the internal breast temperature is shown in Appendix I. The temperature was measured at 9 points on the both breasts, and also the temperature was measured at auxiliary sites.

The tested patients lay on the back with their hands behind their head, in order to normalize the arrangement of the measured points and increase the total accuracy of measurements due to the breasts were flattened naturally in this position.

In order for objectivity to be increased, RTM-diagnosis was carried out independently upon the breast palpation procedure and mammography. The results were compared after the examination of the patients.

With the help of the radiometer 771 women at the age from 16 to 82 years old were examined. They had breast diseases. These data are represented in the table below.

Table 2.

Breast disease	Number of patients	%
Healthy	16	2.1
Fibrocystic mastopathy	367	47.6
Fibroadenoma	60	7.8
Fibrous-fatty involution	37	4.7
Cyst	56	7.3
Mastitis	33	4.3
Diffuse fibrocystic mastopathy	81	10.5
Breast cancer	101	13.1
Ductal papilloma	20	2.6
Total	771	100

During the trial the following diagnostic abilities of the radiometer were investigated :

- differential diagnostics of breast cancer;

- detection where a tumour locates.

For differential diagnosis of breast cancer the following basic criteria were used:

- significant thermal differentials between corresponding points on the right and left breasts;

- an increase in nipple temperature;

- an increase in temperature diversity within one breast.

A malignant tumour may be represented by thermal asymmetry at corresponding points on the left and right breasts and also by a temperature increase in the tumour location in comparison with an average temperature of the breast.

These criteria are formalized and software basing upon them processes and analyzes results of examinations.

Results of Clinical Trial

1. The radiometer has small dimensions, weight and power consumption. It can be easily transferred within a hospital.

2. It is easy to operate the RTM-01 microwave radiometer and the secondary medical staff can operate it. There are no external adjustment elements on the device.

3. Utilization of the device is absolutely harmless for patients and the physicians, therefore the tests can be repeated for the monitoring of treatment.

4. The device was being used for more than 800 hours. Over this period there were no failures.

5. In 86 of 101 studies RTM-results of breast cancer were confirmed by the data of clinical and mammography tests (85 %). 15 cancer patients had no significant thermal abnormality (15%).

157 of 771 patients had all RTM-features of breast cancer (criteria mentioned above), but they were not confirmed by clinical and mammography tests. They are 20.3% of all examined patients.

It is necessary to emphasize that the patients were diagnosed with breast cancer basing only on the data of temperature field measurements. At the same time the use of data received by clinical and mammography examinations in conjunction with radiometry methods will improve the efficiency of the microwave radiometry method.

6. Imaging when the temperature values are linked with measured sites and isotherm lines are drawn through sites having the same temperature help physicals to diagnose.

7. The imperfection of RTM-diagnosis is the RTM-features of acute mastitis are similar to RTM-features of inflammatory cancer (the significant thermal differential). However for clinical practice this imperfection is not essential, as physicians may order a conservative treatment if there are any suspicions of acute mastitis and then repeat RTM-diagnosis. This allows to compare results and analyze dynamics.

In Appendix 2 the thermogram of the healthy woman is shown, in Appendices 3, 4, 5 you can see the thermograms of patients having various types of breast cancer.

Conclusion

The RTM-01 radiometer developed by RES Ltd. is recommended to be used in medical practice for screening at consulting and oncology rooms and at specialized oncology and mammalogy centers for detection of breast cancer and the monitoring of treatment.

Signed by the Head of Department N.V. Vasina

This is a translation, the original is in Russian.

Appendix 1.

Measurement Scheme of Internal Breast Temperature