**Information Sheet *- MBST Study***

 **HOSPITAL**

**The title of the pilot study is “MBST, Magnetic Resonance Therapy In Osteoporosis”**

**Principal Investigator -**

**Name of Organization -**

**Introduction:**

I am Dr , working for Hospital. We are doing a pilot study on osteoporosis which is very common in this country. I will give you information and invite you to be part of this research study. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff*.*

**Purpose of the research**

Osteoporosis is one of the most common and potentially debilitating metabolic diseases in this region. Drugs are used to improve bone condition so that it is less prone to fracture. There is a new treatment without using drugs which may work better. The reason we are doing this research is to find out if this treatment is better than drugs. It is important to remember that drugs can produce side effects.

**Type of Research:**

This research will involve a ten sessions, one hr each of MBST therapy, everyday for two weeks with week end off.

**Participant selection**

We are inviting all patients with osteoporosis/osteopenia, who are already on drug therapy or not to participate in the research on the new non-drug therapy for osteoporosis.

**Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital for osteoporosis. You may change your mind later and stop participating even if you agreed earlier.

**Procedures and Protocol**

A total of patients will be recruited for the study. Each one will be given whole-body MBST Magnetic Resonance Therapy. Patients will undergo a standard assessment (medical history, clinical and laboratory examinations, risk profile, underlying diseases, e.g. osteomalacia, presence of osteoporotic fractures, and medication)

Laboratory Investigation:

Full blood count, erythrocyte sedimentation rate, liver function tests, creatinine, , calcium (ionized and total), and alkaline phosphatase, Vitamin D, parathyroid hormone , thyroid stimulating hormone and free thyroxine. Males should have free testosterone level.

Baseline bone density scan (DXA) will be performed as well as after 3, 6 and 12 months post therapy.

The study will include patients with a bone density as found in osteopenia or manifest osteoporosis. Also included in the trial are patient on antiresorptive or SERM therapy, but no patient is included who is receiving Teriparatide or suffered osteoporotic vertebral fracture. This is to avoid any false positive bone mineral density results.

Patients will receive a basic oral therapy comprising calcium, 600 mg, and Vitamin D3 (1000 IU), and hydrated with approx. 2 litres of fluids prior to Magnetic Resonance Therapy treatment.

The MBST treatments are administered over 10 consecutive weekdays (with a 2-day weekend break), at the same time every day, using a conventional wholebody Magnetic Resonance Therapy couch (Osteo-DolorMed) manufactured by Medtec Medizintechnik, Wetzlar. Each treatment (10x) lasted 1 hour (10 x 1).

**Duration:**

The therapy research takes place as one hour therapy every day for ten days with week end off. Bone mineral density will be measured prior to therapy, at 6 and 12 months post-therapy. We would like to meet with you three, six and 12 months after your last therapy session.

**Side Effects**

The magnitude of the MBST field is around 0.4 milliteslor which is 7500 times less than diagnostic MRI. MRI has been around for nearly 30 years and no adverse effects to date had been reported. Hence, with the very low field magnitude of the MBST, the likelihood of adverse effect/s is highly unlikely.

**Benefits**

Your participation in the research is important and it will help to find an answer if this new modality will improve your bone quality and strength.

**Confidentiality**

We will not be sharing the identity of those participating in the research with anyone.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except your clinician or sponsors.

**Sharing the Results**

The knowledge that we get from doing this research will be shared with you before it is made widely available to the public. Confidential information will not be shared. We will publish the results in order that other interested people may learn from our research.

**Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

**Alternatives to Participating**

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital.

**Who to Contact**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

In the event of a concern or complaint please contact:

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