European, multi-centre, randomised, stratified, parallel-group, open-label, phase III, MRI and Radiograph-based study to evaluate the efficacy of Hyperbaric Oxygen therapy in the treatment of patients with Femoral Head Necrosis.

PATIENT EVALUATION FORM

May 2004

PATIENT DATA

Sex: …….. **Age:** …….

PATIENT HISTORY OF RELEVANCE

Cardiovascular System:

Respiratory System:

Nervous System:

Internal Medicine:

Traumatology and Orthopedics:

Otorinolaryngology:

Ophthalmology:

Other:

Clinical condition associated with FHN

❑ USE OF CORTICOSTEROIDS: ❑ For Systemic Lupus Erythematosus ❑ For Rheumatoid Arthritis ❑ After Renal Transplantation ❑ For Asthma ❑ For Pemphigus ❑ Other ……	❑ ALCOHOL ABUSE
	❑ MYELOPROLIFERATIVE DISORDERS
	❑ COAGULATION DEFICIENCIES
	❑ TRAUMA
	❑ CHRONIC PANCREATITIS
	❑ DECOMPRESSION ILLNESS
	❑ RADIATION

FHN DIAGNOSIS

- ❑ X RAY
- ❑ M.R.I.

- ❑ UNILATERAL
- ❑ BILATERAL

STAGING OF FHN

	RIGHT	*LEFT*
STEINBERG Classification System	❑ No FHN	❑ No FHN
	❑ 0	❑ 0
	❑ 1	❑ 1
	❑ 2	❑ 2
	❑ 3	❑ 3
	❑ 4	❑ 4
	❑ 5	❑ 5
	❑ 6	❑ 6

DATE OF DIAGNOSIS _____ / _____/_____ (dd/mm/yyyy)

Patient data are reported by:

Doctor (name) _____

Hospital/Clinic _____

Address _____

_____

Telephone _____

Fax _____

E-mail _____

- ❑ Orthopaedic Specialist
- ❑ Others

Study Groups:

A Immediate HBO ❑ **B** Delayed HBO ❑

CLINICAL EXAMINATION

❑ Baseline ❑ 2 months ❑ 5 months ❑ 12 months

GAIT

LIMP

❑ Severe or inability to walk
❑ Moderate
❑ Slight
❑ None

SUPPORT

❑ Wheelchair
❑ Two crutches or not able to walk
❑ Two canes
❑ One crutch
❑ Cane most of the time
❑ Cane for long walks
❑ None

DISTANCE WALKED

❑ Bed and chair only
❑ Indoors only
❑ Two or three blocks
❑ Six blocks
❑ Unlimited

ACTIVITIES

STAIRS

❑ Unable to climb stairs
❑ In any manner
❑ Normally using a railing
❑ Normally without using a railing

SHOES/SOCKS

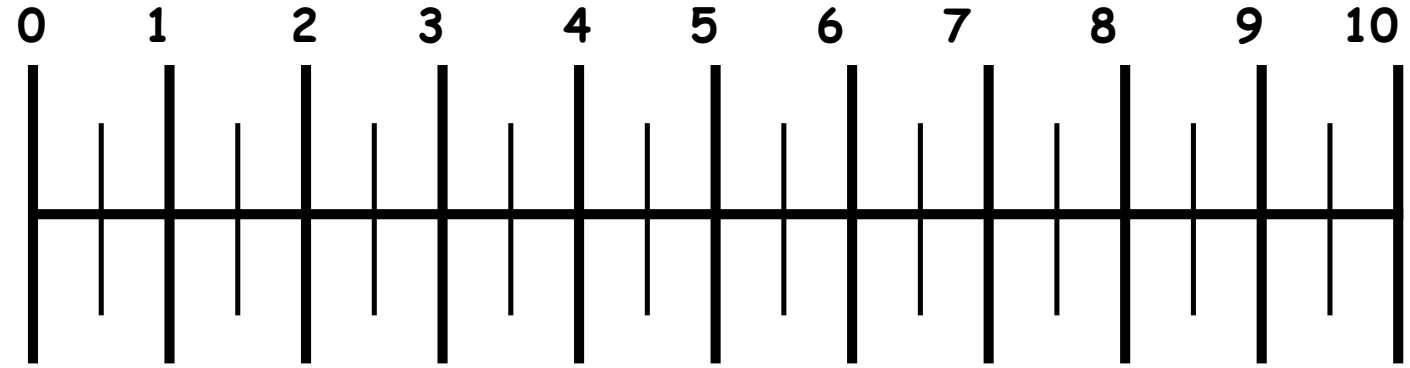
❑ With difficulty
❑ With ease

SITTING

❑ Unable to sit comfortably in any chair
❑ On an high chair for 30 minutes
❑ Comfortably, ordinary chair for one hour

Centre code Patient code Date

Pain Visual Analogue Scale (VAS)



NO PAIN **SEVERE PAIN**

☺ 😐 ☹

PATIENT LYING

RIGHT	***LEFT***
EXTRAROTATION OF LIMB	**EXTRAROTATION OF LIMB**
PAIN SCORE _____	PAIN SCORE _____
INTRAROTATION OF LIMB	**INTRAROTATION OF LIMB**
PAIN SCORE _____	PAIN SCORE _____
BENDING- EXTRAROTATION	**BENDING – EXTRAROTATION**
PAIN SCORE _____	PAIN SCORE _____
BENDING – INTRAROTATION	**BENDING – INTRAROTATION**
PAIN SCORE _____	PAIN SCORE _____
COMPRESSION ON THE "FEMORAL TRIGONUS"	**COMPRESSION ON THE "FEMORAL TRIGONUS"**
PAIN SCORE _____	PAIN SCORE _____

PATIENT WALKING

RIGHT ***LEFT***

PAIN SCORE _____ PAIN SCORE _____

DEAMBULATION POSSIBLE ONLY WITH CRUTCHES

RIGHT ***LEFT***

PAIN SCORE _____ PAIN SCORE _____

DEAMBULATION NOT POSSIBLE FOR PAIN

RIGHT ***LEFT***

PAIN SCORE _____ PAIN SCORE _____

NIGHT PAIN

RIGHT ***LEFT***

PAIN SCORE _____ PAIN SCORE _____

X-RAY **(baseline, 5 and 12 months)** ❑ **Yes** ❑ **No** **Date:** ……

Report:

……

……

……

M.R.I. **(baseline, 5 and 12 months)** ❑ **Yes** ❑ **No** **Date:** ……

Report:

……

……

……

ASSOCIATED THERAPY

PAIN CONTROL

❑ Yes DRUG/S: .....

.....

❑ No DOSAGE: .....

Patient data are reported by:

Doctor (name) _____

Hospital/Clinic _____

Address _____

_____

Telephone _____

Fax _____

E-mail _____

Study Group

HYPERBARIC OXYGEN THERAPY

HBO PROTOCOL							
Day	Date	KPa	Lenght (min.)	No. of O_2 periods	Lenght of each O_2 period (min.)	no. of air intervals	Lenght of each air interval (min.)
1							
2							
3							
4							
5							
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Comments:

ADVERSE AND SIDE EFFECTS FORM

Note any adverse effect you suspect from any of given treatment

- ❑ Barotrauma of the Ear:
  - ❑ Teed 1°
  - ❑ Teed 2°
  - ❑ Teed 3°
  - ❑ Teed 4°
- ❑ Round or Oval Window blow-out
- ❑ Sinus squeeze
- ❑ Visual refractive changes
- ❑ Cataracts
- ❑ Numb fingers
- ❑ Dental problems
- ❑ Claustrophobia
- ❑ Seizures
- ❑ Pulmonary Oxygen Toxicity
- ❑ Others _____

PATIENT INFORMED CONSENT AND CONSENT FORM

European, multi – center, randomized, stratified, parallel group, open label, phase III, MRI and Radiograph – based study to evaluate the efficacy of Hyperbaric Oxygen therapy in the treatment of patients with Femoral Head Necrosis.

Patient data are reported by:

Doctor (name) _____

Hospital/Clinic _____

Address _____

_____

Telephone _____

Fax _____

E-mail _____

Hyperbaric Unit: _____

Orthopedic Centre: _____

PURPOSE OF THE STUDY

You are being asked to participate voluntarily in a research study because you undergo an orthopedic problem of your femoral head, known as femoral head necrosis (FHN).
FNH is a condition in which the blood supply to the femoral head is compromised.
The progression of the disease implies pain, arthritic changes and possible collapse of the femoral head.
The treatment of the FHN is an unresolved orthopedic problem, and multiple approaches are used for its management, with or without surgical procedures.
Hyperbaric oxygenation (HBO) is one of the non-interventional methods and is the proposed way of treatment in this study of FHN.

TESTED THERAPY - DESCRIPTION OF THE STUDY

HBO treatment consists in breathing oxygen under pressure.
For this you will need to be treated inside an air-tight room (hyperbaric chamber), breathing oxygen through a face mask for about one and a half hours, once a day, five days a week.
Through this procedure oxygen in hyperbaric conditions acts like a drug, targeting the bone restoration but only in the initial stages of this lesion.

Although this technique has been employed for several years with good results on the HFN recovery, the actual scientific knowledge does not allow to conclude that it is more effective than if no treatment would have been given at all ("therapeutic abstention").
In order to establish the HBO efficacy two groups (plus HBO, versus non HBO) will be evaluated by means of clinical, radiographic and MRI evaluation.
So, the goal of this study is to compare the results of HBO therapy to an absence of treatment.
If you agree to participate in the study, and in order to make it scientifically valid, you will be allocated into one of these groups by randomisation.
The current study will be performed in many European Hyperbaric centers in different countries, always attached and in close collaboration with orthopedic departments.

STUDY PROCEDURE

If you will agree to participate our physician will discuss the purpose and the procedures of this study with you.
Complete physical examination, blood sample, radiographic and MRI examination will take place (if not already done) in regular intervals during and at the end of the study.
All randomized patients will receive the conventional non – surgical therapy that means non-weight bearing and pain control drugs.
The HBO group will receive additionally 60 treatments in a maximum period of 5 months (once a day, five times a week).
Your cooperation in this study is greatly appreciated. However, it is important that you know there is no obligation imposed upon you: you can freely decide on any moment to stop your participation in the study.
If you are allocated for the group without HBO it's possible that at the end of the study period, according to your orthopaedist evaluation, HBO treatment may be proposed regardless of your previous participation in the study.

RISKS AND DISCOMFORT

The side effects of this treatment are rare and not serious, if you follow carefully the instructions of the staff of the treatment facility.
The hyperbaric specialist before your inclusion in this study will evaluate situations where HBO may be related to side effects or other additional risks.
If during the treatment you will present symptoms or discomfort that may interfere with your safety according to your physician's opinion, you will be asked to discontinue permanently or periodically.

POTENTIAL BENEFIT

The prevention of the FHN development is not guaranteed, but clinical experience so far has shown very encouraging results

However, by participating in this study you will help to obtain important additional information about the ability of HBO to prevent the femur bone collapse, if applied properly and on time.

CONFINDENTIALITY

All information obtained during this study, including hospital records, personal data and research data will be kept confidential.

INFORMED CONSENT

It is a legal obligation for us to ask you, to sign this declaration, preceded by the handwritten mention: "read and approved". This declaration will remain confidential and will be joined to your medical file.

I who sign *(name + first name)*

.....

declare that I have been informed fully about the study in which I am about to take part, as well as about the treatment I will receive, the possible side-effects and complications.

I know that on any moment, I may choose to end my cooperation in this study.

(read and approved)

Date: Signature:

STATEMENT OF TREATING PHYSICIAN

I have fully explained the conditions of the trial, including the uncertainty of the efficacy of the HBO treatment and the possible complications, which may occur. To the best of my understanding …….. (name of patient), fully comprehends these HBO trial conditions.

Name of Physician: _____

Date: _____ Signature: _____