

Action COST B14

SUBJECT NUMBER	SUBJECT INITIALS
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# ADVERSE EVENTS

## HBO in the treatment of diabetic foot lesion.

List any adverse events with onset after initiation of study including worsening of pre-existing conditions.

CHECK IF NONE

AE #	Adverse Event (one event per line)	Serious ?	Onset Date (dd-mm-yyyy)	Resolution Date (dd-mm-yyyy)	Severity	Frequency	Action Taken			Outcome	Relationship to Study
							Study Drug	Other	If Other = 99, specify below		
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A. SERIOUS : Fatal, life-threatening, disability (significant, persistent or permanent, requires or prolongs hospitalization, congenital anomaly or malignancy, or requires medical/surgical intervention to prevent permanent impairment or damage.  
1 = Yes  
2 = No

B. SEVERITY :  
1 = Mild  
2 = Moderate  
3 = Severe  
4 = Life Threatening

C. FREQUENCY :  
1 = Single / Continuous  
2 = Intermittent  
D ACTION TAKEN :  
1 = None  
3 = Dose reduced, interrupted or therapy delayed  
4 = Study stopped permanently due to AE

E. ACTION TAKEN – OTHER :  
1 = None  
2 = Uncertain  
4 = Procedure or physical therapy  
5 = Blood or blood products  
6 = Withdrawn from study due to AE  
8 = Prescription Drug therapy  
9 = Non-Prescription Drug therapy  
10 = Hospitalization  
11 = IV Fluids  
99 = Other (specify above)

F. OUTCOME :  
1 = Complete recovery or return to baseline  
2 = Alive with sequelae  
3 = Death  
4 = Unknown / lost to follow-up  
5 = AE persisting

G. RELATIONSHIP :  
1 = None  
2 = Possibly Related  
4 = Probably Related

All serious events must be reported

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Within 48 hours