KKS
Koordinierungszentrum für Klinische Studien
Medizinische Universität Innsbruck

MEDIZINISCHE UNIVERSITÄT
INNSBRUCK

OE Clinical Trial Center

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Leitung
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LEODOR TRIAL

Pre-Study – Feasibility Questionnaire

Study title:	Repetitive levosimendan infusions for patients with advanced chronic heart failure (LeoDOR)
Protocol (version, date):	1.0
EudraCT-No.:	*will be applied*
IMP:	Levosimendan (Simdax®)

Site No.:	e.g. AUT01
PI (name/address):	Title, name Institution Address, zipcode, city
Substitute (name/address):	Title, name Institution Address, zipcode, city

STUDY TEAM		
	YES	NO
Principal investigator has more than two years of experience conducting studies.		
Practical experience with Levosimendan?		
Familiarity with ICH-GCP and national regulations on the performance of clinical trial on medicinal products ?		
How many studies did you perform as principal investigator (in general)?		

Team Members	
Principal Investigator	
Investigator	
Investigator	
Investigator	
Pharmacist	
Designated person for the lab	
Study Coordinator	
Study Nurse	
Other:	

Contact details	
Study coordinator/-nurse:	Name
	Institution
	Address, zipcode, city
	Phone, E-mail

CONFLICT OF INTEREST (COI)		
	YES	NO
Existing conflict of interest?[1]		

[1] If YES, please explain the existing COI:

REGISTRATION		
	YES	NO
Does the study site have to register/apply for conduct of this study to hospital management?	[2]	
Does the study site have to register this study in any other registers or other local databases?	[2]	

[2] If YES, please mention name of local database:

STUDY DESIGN			
	YES	NO	[3] If YES, please comment:
Do you have any questions on the scientific background and objectives?	[3]	☐	
Do you have any questions on the process of study/specific examinations?	[3]	☐	
Do you have any questions on the timelines (start, end and time of recruitment)?	[3]	☐	
Treatment			
Please choose **one** of the below listed options. Please note that the treatment group you choose is obligatory for the whole study duration as the randomization will be done accordingly.			
Treatment group: 6h-infusion every 2 weeks			
Treatment group: 24h-infusion every 3 weeks			
BOTH treatment groups			

ETHICS COMMITTEE		
EC name Address, zipcode, city Country *(Name and address of ethics committee)*		
Name *(Name of ethics committee's chairman)*		
Is someone simultaneously member of the study team and the ethics committee?	YES	NO
How often are ethics committee meetings conducted?	x per month	
Date of next three meetings, starting with July/August 2017:	1. meeting:	(insert date)
	2. meeting:	(insert date)
	3. meeting:	(insert date)
	4. meeting:	(insert date)

PHARMACY	
Is a pharmacy involved in the study and has the study medication to be send directly to the pharmacy?	
YES	☐ NO
Name and address of pharmacy:	**Name and address of alternative institution:**
Name	Name
Institution	Institution
Address, zipcode, city	Address, zipcode, city
Name of person responsible:	**Name of person responsible:**
Name	Name
Institution	Institution
Address, zipcode, city	Address, zipcode, city
Phone, E-mail	Phone, E-mail

	YES	NO
Are secured storage rooms/lockable cabinets available in order to provide access only by authorized site staff?		
Is a refrigerator providing adequate storage conditions (2-8°C, light protected) available?		
Is the refrigerator providing enough space for study medication?		

AVAILABILITY OF PATIENTS			
	YES	NO	Comments
Do you have any restrictions or do think that any exclusion or inclusion criteria may influence recruitment?			
Enough patients recruitable?			
How many new patients per month are treated at your site?			
How many patients do you feel you could realistically enroll in this study per year/quarter?			
How many patients fulfilled the inclusion criteria during the last year/quarter?			
Please give an estimation on how many patients will possibly drop-out during the study:	(estimated percentage)		
How many patients of the study site are participating in clinical studies?	(total number or estimated percentage)		

EVALUATION OF STUDY SITE			
	YES	NO	Comment
Does the study site provide a freezer (-80°C)?			
Does the freezer (-80°C) at the study site hold enough space for the samples? You will need four 96-well racks per study patient.			
Does the study site provide a centrifuge (1600g)?			
Space for monitoring is available. Where?		☐	
Language			
Please indicate the language of documentation (e.g. worksheets, patient files) at your study site:			
Source data			
a) If source data is only available electronically:	YES	NO	Comment
Access rights for monitor defined	☐	☐	if not applicable, how will SDV be enabled?
Security system (description available)	☐	☐	
Audit trail implemented	☐	☐	
b) If source data is available in paper form:	YES		NO
Are secured storage rooms/lockable cabinets available in order to provide access only by authorized site staff?			☐
Where is source data stored?			

Do you want to take part in the LeoDOR trial including acceptance to all formal requirements including GCP, national laws, audits, archiving, etc.?

☐YES

☐NO

(date)	(signature PI)	(name in block capital)