

Non Serious Adverse Drug Reactions Report

Start Date:2016-06-08 End Date:2016-06-09

Study :EMR700623-541	Investigator :Ying Zhong	Country of Investigator :China	SiteNo:C05			
Subject No :C05-0117	Subject Initials :Y-L	DOB :04/16/1982	Sex:Female	Race:Asian	Height:165cm	Weight:48kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/23/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/08/2015	09/10/2015		Related	Mild	
Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
Protocol procedure**, Concomitant medication**(Other value:)	Dose reduced	Led to study termination	Resolved			
Event Description:abdominal distention;ascites;Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 19-Aug-2015 / 21-Aug-2015						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition	Start Date	Related to study condition	Ongoing			

08-JUN-16

Ying
Zhong/EMR700623-541/C05-0117

