

Non Serious Adverse Drug Reactions Report

Start Date:2016-06-23 End Date:2016-06-24

Study :EMR700623-541	Investigator :Ying Zhong	Country of Investigator :China	SiteNo:C05			
Subject No :C05-0001	Subject Initials :XFZ	DOB :01/21/1988	Sex:Female	Race:Asian	Height:159cm	Weight:50kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/01/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	08/16/2015	08/18/2015		Related	Severe	
Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
None(Othervalue:)	Not applicable	None	Resolved			
Event Description:Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition	Start Date	Related to study condition	Ongoing			
oophorocystectomy	UK-Jul-2013	Not on treatment/medication				
salpingoplasty	UK-Feb-2014	Not on treatment/medication				
salpingitis after previous tubal occlusion	UK-Feb-2014	Not on treatment/medication	Ongoing			

23-JUN-16

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Zhong/EMR700623-541/C05-0001

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Start Date:2016-06-23 End Date:2016-06-24

Study :EMR700623-541	Investigator :Ying Zhong		Country of Investigator :China	SiteNo:C05		
Subject No :C05-0021	Subject Initials :FYZ	DOB :08/28/1990	Sex:Female	Race:Asian	Height:150cm	Weight:45kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/04/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	08/19/2015	08/21/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Protocol procedure**,Concomitant medication**(Othervalue:)		Not applicable	None	Resolved		
Event Description:abdominal distention;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:Yes						
Condition				Start Date	Related to study condition	Ongoing
salpingocatheterism				UK-Unk-2012	Not on treatment/medicatio n	

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