

Non Serious Adverse Drug Reactions Report

Start Date:2016-07-20 End Date:2016-07-21

Study :EMR700623-541	Investigator :Ying Zhong	Country of Investigator :China	SiteNo:C05			
Subject No :C05-0041	Subject Initials :W-Y	DOB :07/03/1981	Sex:Female	Race:Asian	Height:153cm	Weight:55kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/08/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	08/23/2015	08/25/2015		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:)	Dose not changed	Led to study termination	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 21-Aug-2015 / 25-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			

21-JUL-16

Ying
Zhong/EMR700623-541/C05-0041

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Start Date:2016-07-20 End Date:2016-07-21

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**(Othervalue:)		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

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Non Serious Adverse Drug Reactions Report

Start Date:2016-07-20 End Date:2016-07-21

Study :EMR700623-541	Investigator :Ying Zhong		Country of Investigator :China	SiteNo:C05		
Subject No :C05-0132	Subject Initials :HQL	DOB :07/16/1980	Sex:Female	Race:Asian	Height:166cm	Weight:57kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	08/27/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/08/2015	09/16/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Disease under study**(Othervalue:)		Dose not changed	None	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
Fallopian tube repair anaplasty				UK-Unk-2011	Not on treatment/medicatio n	

21-JUL-16

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