

Non Serious Adverse Drug Reactions Report

Start Date:2016-07-26 End Date:2016-07-27

Study :EMR700623-541	Investigator :Fei Gong	Country of Investigator :China	SiteNo:C01			
Subject No :C01-0158	Subject Initials :T-Y	DOB :06/17/1983	Sex:Female	Race:Asian	Height:163cm	Weight:3300g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	09/16/2015	112.5				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	10/12/2015	10/12/2015		Related	Moderate	
Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
None(Othervalue:)	Not applicable	Concomitant procedure**	Resolved			
Event Description:Abdominal distension, Nausea, yellow urine with less volume, chest pelvic effusion,ascites puncture 12-Oct-2015,2500ml						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition	Start Date	Related to study condition	Ongoing			
right fallopian tube is less patency,left fallopian tube is obstruction	06/04/2015	Not on treatment/medication	Ongoing			
Endometrial polyps hyperplasia	08/24/2015	Not on treatment/medication	Ongoing			

26-JUL-16

Fei Gong/EMR700623-541/C01-0158

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Start Date:2016-07-26 End Date:2016-07-27

Study :EMR700623-541	Investigator :NA	Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-049	Subject Initials :PGR	DOB :02/20/1983	Sex:Female	Race:Asian	Height:168cm	Weight:62g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/02/2015	300				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/13/2015	05/29/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Concomitant medication **	Resolved		
Event Description:albumin treatment and resloved						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
laparoscopic ovary cystectomy				UK-UNK-2004	Not on treatment/medication	

26-JUL-16

NA/EMR700623-541/k01-049

