Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :Fei Gong		Country of Investigator :China	SiteNo:C01		
Subject No :C01-0001	Subject Initials :TTW	DOB :05/13/1988	Sex:Female	Race:Asian	Height:157cm	Weight:41.5kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/16/2015	112.5	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/06/2015	06/15/2015		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:Nausea, vomiting, yellow urine with less volume, chest pelvic effusion,ascites puncture 10-Jun-2015,2200ml;ascites puncture 15-Jun-2015,2900ml;

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
Bilateral fallopian tube obstruction	04/11/2014	Not on treatment/medication	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :Fei Gong		Country of Investigator :China	SiteNo:C01		
Subject No :C01-0068	Subject Initials :X-S	DOB :04/16/1989	Sex:Female	Race:Asian	Height:160cm	Weight:43kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	06/27/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	07/23/2015	08/04/2015		Related	Severe

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Concomitant procedure**	Resolved		

Event Description:Abdominal distension, Nausea, yellow urine with less volume, chest pelvic effusion , Ascites puncture 23Jul2015,1000ml; 27Jul2015,2100ml; 30Jul2015,2500ml; 04Aug2015,2000ml ;

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
The left Hydrosalpinx and adhesions,less patency.Right fallopian tube partially blocked	03/22/2014	Not on treatment/medication	Ongoing
right fallopian tube resection because of Ectopic pregnancy	UK-Oct-2011	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0010	Subject Initials :Y-H	DOB :10/18/1985	Sex:Female	Race:Asian	Height:153cm	Weight:47.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/11/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/29/2015	06/02/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Concomitant medication**(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description:Moderate OHSS occurs canceled transplant						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0102	Subject Initials :HYD	DOB :10/14/1985	Sex:Female	Race:Asian	Height:163cm	Weight:57.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/19/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS risk				Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	None			
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
Palace laparoscopy				Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0178	Subject Initials :XSC	DOB :10/11/1988	Sex:Female	Race:Asian	Height:155cm	Weight:54.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/27/2015	200	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/10/2015	06/16/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	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
HSG: bilateral tubal resistance.	Uk-Jan-2013	Not on treatment/medication	
Laparoscopy surgery: pelvic adhesions dissection, bilateral salpingo-repair plastic surgery, normal uterine shape.	Uk-Jan-2013	Not on treatment/medication	
Hysteroscopy normal, water surgery: incomplete right fallopian tube obstruction	Uk-Feb-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0179	Subject Initials :HYZ	DOB :05/14/1991	Sex:Female	Race:Asian	Height:158cm	Weight:53.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/27/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/11/2015	06/16/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	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
Ectopic pregnancy laparotomy: the left fallopian tube removal.	Uk-Unk-2009	Not on treatment/medication	
Abdominal ectopic pregnancy conservative surgery.	Uk-Unk-2010	Not on treatment/medication	
Hysteroscopy: endometrial polyp excision.	Uk-Jan-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0180	Subject Initials :YPW	DOB :08/20/1982	Sex:Female	Race:Asian	Height:156cm	Weight:57.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/27/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/13/2015	06/16/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	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
Ectopic pregnancy: treatment of chemical drugs to kill embryos	Uk-Unk-2012	Not on treatment/medication	
HSG: bilateral tubal occlusion	Uk-Unk-2008	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0185	Subject Initials :YMX	DOB :09/07/1975	Sex:Female	Race:Asian	Height:159cm	Weight:63.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/28/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/15/2015	06/20/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	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
HSG: bilateral tubal occlusion	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0190	Subject Initials :F-H	DOB :03/09/1984	Sex:Female	Race:Asian	Height:160cm	Weight:55.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/28/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/12/2015	06/16/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0191	Subject Initials :SYZ	DOB :02/16/1983	Sex:Female	Race:Asian	Height:162cm	Weight:58.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/28/2015	200	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/14/2015	06/18/2015		Related	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Not applicable	Led to study termination	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
HSG: bilateral tubal occlusion with effusion	Uk-Unk-2008	Not on treatment/medication	
Tubal treatment: Tips patency	Uk-Unk-2008	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

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:)	Dose not changed	Concomitant medication **	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
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

06-APR-16

Ying Zhong/EMR700623-541/C05-0001

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-0059	Subject Initials :LKH	DOB :08/05/1981	Sex:Female	Race:Asian	Height:153cm	Weight:74kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	06/02/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/13/2015	07/02/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-035	Subject Initials :PSS	DOB :01/19/1983	Sex:Female	Race:Asian	Height:161cm	Weight:56kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	03/11/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/23/2015	04/21/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-036	Subject Initials :JSY	DOB :07/28/1981	Sex:Female	Race:Asian	Height:162cm	Weight:54kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	03/13/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/24/2015	04/07/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-040	Subject Initials :LBH	DOB :03/05/1985	Sex:Female	Race:Asian	Height:164cm	Weight:61kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	04/06/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	04/15/2015	04/30/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Led to study termination	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

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:62kg
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 **,Led to study termination	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	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-05 End Date:2016-04-06

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-050	Subject Initials :KHG	DOB :04/22/1984	Sex:Female	Race:Asian	Height:150cm	Weight:46kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/03/2015	300	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/14/2015	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:)	Dose not changed	Led to study termination	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
ovary cystectomy	UK-Jan-2014	Not on treatment/medication	