Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0024	Subject Initials :HXG	DOB :10/06/1992	Sex:Female	Race:Asian	Height:150cm	Weight:55.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/12/2015		200			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/30/2015	06/05/2015		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:Moderate OHSS patients, improved canceled after embryo transfer.						
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:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0028	Subject Initials :XHL	DOB :04/12/1981	Sex:Female	Race:Asian	Height:158cm	Weight:65.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/12/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/25/2015	06/03/2015		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:Moderate OHSS patients, improved canceled after embryo transfer.

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
Left abdominal ectopic pregnancy salpingectomy	Uk-Unk-2002	Not on treatment/medication	
Right next laparoscopic tubal ectopic pregnancy surgery	Uk-Unk-2010	Not on treatment/medication	
Conservative treatment of ectopic pregnancy	Uk-Unk-2004	Not on treatment/medication	
Conservative treatment of ectopic pregnancy	Uk-Unk-2005	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0045	Subject Initials :H-T	DOB :09/08/1983	Sex:Female	Race:Asian	Height:158cm	Weight:57.5kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/13/2015	250	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/28/2015	06/05/2015		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:Moderate OHSS occurs canceled embryo transfer, OHSS improvement

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
Hysteroscopic polypectomy	Uk-Aug-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0063	Subject Initials :HMC	DOB :07/25/1981	Sex:Female	Race:Asian	Height:162cm	Weight:50.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/15/2015	250	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/29/2015	06/05/2015		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:Moderate OHSS occurs canceled embryo transfer, OHSS improvement

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
Hysteroscopic surgery through liquid	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0083	Subject Initials :Y-L	DOB :08/20/1988	Sex:Female	Race:Asian	Height:158cm	Weight:54.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/18/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/31/2015	06/05/2015		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:Moderate OHSS patients, improved canceled after embryo transfer.

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 pelvic sticky points left salpingostomy	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0086	Subject Initials :YZZ	DOB :07/07/1987	Sex:Female	Race:Asian	Height:150cm	Weight:55.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/18/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/01/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description:Moderate OHSS occurs canceled embryo transfer, OHSS improvement						
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:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0088	Subject Initials :HLK	DOB :06/14/1986	Sex:Female	Race:Asian	Height:159cm	Weight:59.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/18/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/30/2015	06/05/2015		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:Moderate OHSS occurs canceled embryo transfer, OHSS improvement

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 laparoscopic pelvic surgery sticky points, bilateral tubal plastic surgery, endometriosis lesions fulguration.	Uk-Unk-2012	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0089	Subject Initials :XYZ	DOB :06/12/1986	Sex:Female	Race:Asian	Height:152cm	Weight:48.5kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/18/2015	187.5	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/04/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS patients, improved canceled after embryo transfer.

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
Sticky points pelvic laparoscopy surgery, tubal surgery to clear	Uk-Nov-2012	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0095	Subject Initials :MLG	DOB :08/19/1990	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	05/19/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/31/2015	06/05/2015		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:Moderate OHSS occurs canceled embryo transfer, OHSS improvement						
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:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0103	Subject Initials :CPZ	DOB :05/12/1989	Sex:Female	Race:Asian	Height:165cm	Weight:63.5kg
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	06/02/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS patients, improved canceled after embryo transfer.

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 right side of the open line on the right side of salpingectomy tubal pregnancy	Uk-Unk-2011	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0111	Subject Initials :CXW	DOB :10/10/1979	Sex:Female	Race:Asian	Height:162cm	Weight:68.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/20/2015		200			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/02/2015	06/12/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		

Event Description:Moderate OHSS patients, improved canceled after embryo transfer.

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 laparoscopic surgery, the left fallopian tube embryo window.	Uk-Unk-2012	Not on treatment/medication	
Tubal lipiodol angiography	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

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	08/28/2015		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

30-MAY-16

Ying Zhong/EMR700623-541/C05-0041

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-30 End Date:2016-05-31

Study :EMR700623-541	Investigator :Ying Zhong		Country of Investigator :China	SiteNo:C05		
Subject No :C05-0056	Subject Initials :X-P	DOB :06/14/1983	Sex:Female	Race:Asian	Height:158cm	Weight:46kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	08/13/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	08/27/2015	08/29/2015		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	Led to study termination	Resolved		

Event Description:abdominal distention;nausea ;ascites;Drug : Hydroxyethyl Starch 130/0.4 and Sodium Chloride Injection 500ml , ivgtt bid calcium gluconate injection 10ml+dextrose injection 500ml ivgtt qd 17-Aug-2015 / 27-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

30-MAY-16

Ying Zhong/EMR700623-541/C05-0056