

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-12 End Date:2016-05-13

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0059	Subject Initials :J-L	DOB :12/23/1984	Sex:Female	Race:Asian	Height:155cm	Weight:50.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/14/2015	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			

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Start Date:2016-05-12 End Date:2016-05-13

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0062	Subject Initials :FQR	DOB :07/25/1983	Sex:Female	Race:Asian	Height:162cm	Weight:46.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/14/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/30/2015	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
Hysteroscopic tubal inspection				Uk-May-2014	Not on treatment/medication	

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Start Date:2016-05-12 End Date:2016-05-13

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0071	Subject Initials :LLX	DOB :07/13/1987	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	05/15/2015	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:Yes						
Condition				Start Date	Related to study condition	Ongoing
Laparoscopic pelvic sub sticky, sticky points left fallopian tube surgery.				Uk-Unk-2014	Not on treatment/medication	

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Non Serious Adverse Drug Reactions Report

Start Date:2016-05-12 End Date:2016-05-13

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0115	Subject Initials :KJT	DOB :07/02/1988	Sex:Female	Race:Asian	Height:163cm	Weight:52.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/21/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/05/2015	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
HSG examination: bilateral tubal occlusion				Uk-Unk-2012	Not on treatment/medication	
Laparoscopy surgery: pelvic sticky points, bilateral tubal ostomy + right side mesosalpinx cyst removal.				Uk-May-2015	Not on treatment/medication	

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Non Serious Adverse Drug Reactions Report

Start Date:2016-05-12 End Date:2016-05-13

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0118	Subject Initials :MLF	DOB :08/03/1984	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	05/21/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/07/2015	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:Yes						
Condition				Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction				Uk-Unk-2007	Not on treatment/medication	
Laparoscopic pelvic sticky points, bilateral ovarian drilling				Uk-Unk-2007	Not on treatment/medication	
Cervical biopsy showing inflammation				Uk-Unk-2015	Not on treatment/medication	

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Non Serious Adverse Drug Reactions Report

Start Date:2016-05-12 End Date:2016-05-13

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0126	Subject Initials :RCM	DOB :01/09/1989	Sex:Female	Race:Asian	Height:165cm	Weight:60.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/21/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/07/2015	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
HSG: the right fallopian tube obstruction, poor uterine shape				Uk-Unk-2013	Not on treatment/medication	
Hysteroscopy: uterine spindle-shaped, single horn.				Uk-Unk-2014	Not on treatment/medication	

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Start Date:2016-05-12 End Date:2016-05-13

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0134	Subject Initials :QYL	DOB :06/17/1986	Sex:Female	Race:Asian	Height:155cm	Weight:47.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/22/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/06/2015	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:Yes						
Condition				Start Date	Related to study condition	Ongoing
Laparotomy: pelvic abscess incision and drainage, the right accessories cystectomy				Uk-Unk-2009	Not on treatment/medicatio n	
Hysteroscopy normal uterine shape				Uk-Unk-2013	Not on treatment/medicatio n	
Hysteroscopic curettage				Uk-Unk-2015	Not on treatment/medicatio n	

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